Editorial

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Mid-year Meeting

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Maryland Pharmacist

WINTER 2018

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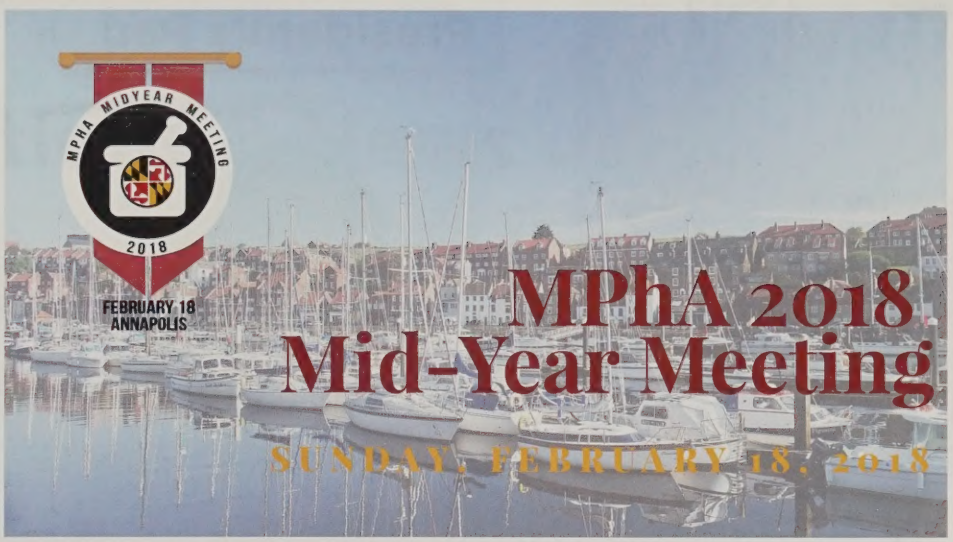

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CONTRIBUTORS
NASPA Services Company, LLC, Editorial
Katy Pincus, PharmD, BCPS
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Maryland Pharmacists Association, 9115 Guilford Road, Suite 200, Columbia, MD 21046, call 443.583.8000, or email aliyah.horton@mdpha.com.

President's Pad

Dear MPhA Members:

Tis the season...For Advocacy!

When we think of the word advocacy, those of us in Maryland think of the numerous Maryland Pharmacy Coalition Legislative Days we've had over the years. The truth is that advocacy for pharmacy does not only happen that day, but it can happen every day in various ways. We know that many of you may not be able to join us on Legislative Day for various reasons, but please know that your efforts do not go unnoticed, and every action, no matter how small, can make an impact, but you do have to make a choice to act. It is simply amazing what we can accomplish when everyone can contribute their support to pharmacy.

I have been fortunate over the years to be involved in various legislative efforts for pharmacy, from immunizations to point of care testing, and all along the way I have had the support of my colleagues at MPhA. They joined me at hearings, testified alongside me, worked to review proposed regulations, attended work groups, and educated legislators about various issues. What has always amazed me about this process was it really started with people believing in a cause and giving what they could to support it in any way they could. The efforts we have made to become #ProviderReady did not start just a few years ago, but actually a few decades ago, and our current experience tells us that Provider Status will not come easy. It will take a few years for the idea to take hold, but now is the time to help us establish those roots that will ensure that as a profession we will be ready to take on that responsibility serving our patients at a higher level. Reimbursement continues to be a challenging issue for many of our members, and we are working to ensure that the impact of those issues is being shared and discussed with various stakeholders. To continue to support successes and address practice challenges, here are some ways you can help advocate:

- **Be informed:** Knowing the issues that affect practice will help you understand your role further in helping support the various efforts of MPhA and our pharmacy colleagues.
- **Tell your story:** We are surrounded by amazing practitioners here in Maryland who are already serving their patients and communities in many ways. Sharing what you do will help others understand the role of the pharmacist in providing care, and understanding what impact establishing pharmacists formally as providers will have on health care in Maryland.
- **Contact your legislators:** As Maryland residents, our legislators represent us and can only know us if we are sharing with them on a regular basis. It is likely that our issues also impact their other constituents as well, so serving as a resource can have an amazing impact.
- **Be present:** If you are able, join us at events like MPC Legislative Day, testify at hearings, or join us for work groups. It is helpful for us to share how various issues impact our membership as a whole, and MPhA can only know that if you join us to share and talk. Supporting your pharmacy colleagues will help show that we are unified in our mission to strengthen our profession.

The MPC Legislative Day is February 20th! Register today to join us either in the morning for meetings with legislators and their aides or at the evening reception from 6:30-8:30pm. Please visit marylandpharmacist.org for more information.

While we have entered our Maryland Legislative season, advocacy efforts take place all year long. I hope that you can join MPhA in our efforts all year long to support the profession of pharmacy!

Kindest regards,

Cherokee Layson-Wolf
President

Member Mentions & News You Can Use

McPherson Named Visionary in Hospice and Palliative Medicine

Mary Lynn McPherson, PharmD, MA, MDE, BCPS, CPE, professor and executive director of advanced post-graduate education in palliative care in the Department of Pharmacy Practice and Science (PPS) at the University of Maryland School of Pharmacy has been named a Visionary in Hospice and Palliative Medicine by the American Academy of Hospice and Palliative Medicine (AAHPM).

"This program recognizes key individuals who have been critical in building and shaping our field over the past 30 years," says Steve R. Smith, MS CAE, chief executive officer for AAHPM. "These individuals represent thousands of other health care professionals in this country who provide quality medical care and support for those living with serious illness — each and every day."

Congratulations Mary Lynn!

Maryland Students Elected to APhA-ASP

Two students from Maryland were elected as APhA-ASP Region 2 Delegates: Elodie A. Tendoh from University of Maryland and Seth Weinstock from the University of Maryland Eastern Shore. Elodie and Seth were elected as delegates at the Midyear Regional Meeting in Pittsburgh this past November. Congratulations Elodie and Seth!

APhA-ASP
AMERICAN PHARMACISTS ASSOCIATION
ACADEMY OF STUDENT PHARMACISTS
APhA

New Addition to the MPhA Pharmily!

Congratulations to Deanna Tran and Chai Wang, who welcomed their first child, daughter, Cassandra Hope Wang on December 15th at 10:58am. She weighed in at a healthy 7 lbs, 6 oz.

WELCOME NEW MPhA MEMBERS

Mir Karamat Ali
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Anupam Bhavsar
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Archana Zala

Interview: Lieutenant Chris Charles

By Miaka Huynh, PharmD Candidate 2018, Notre Dame of Maryland University, MPhA APPE Rotation Student

Eight months ago, Chris Charles, PharmD, BCPS, AE-C, an active member of Maryland Pharmacists Association (MPhA) moved across the United States and settled in South Dakota. Chris joined Indian Health Service within the United States Public Health Service (USPHS) and is now known as Lieutenant (LT) Charles. He is currently serving on the Pine Ridge Indian Reservation, home to the Oglala Lakota Sioux Nation. In 2000, the United States Census Bureau reported an employment rate of 57% on the reservation with 61% of individuals living below the poverty level. It goes without saying that LT Charles' knowledge and skills are greatly needed. As busy as he is with work and family (with a new baby on the way), he graciously made time for an interview with MPhA.

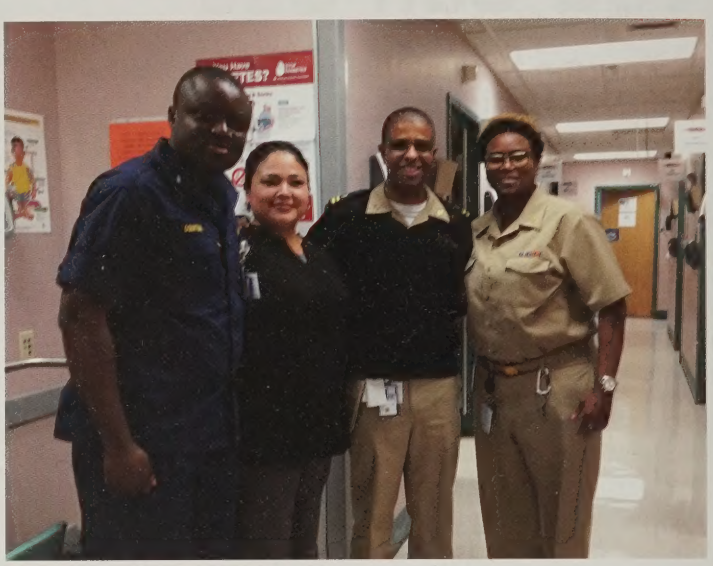
What inspired you to join the Indian Health Service (IHS)?

When I was in pharmacy school, about 11 years ago, I met CAPT James Bresette. He was there to do a presentation on the cool things that pharmacists could do within the Corps [United States Public Health Service]. From there, I learned that the Indian Health Services (IHS), and more generally, the Corps, gives you the opportunity to do more and practice to the top of your license. The IHS give you an opportunity to work in a variety of areas and that's what inspired me to join.

Being far from resource rich urban centers, you are needed more and it gives you the opportunity to do more. Because we have so many different areas, we don't have to work just as outpatient pharmacists. I don't have to be a specialist to go to work in a broad range of clinical settings.

Where is your post/location?

At the Pine Ridge Reservation, our hospital has 40 beds and we serve about 20,000 people. The hospital has acute care, emergency department, optometry, dental, physical therapy, outpatient primary care clinic, mid-wife clinic, ENT (Ear, Nose, and Throat) clinic, behavioral health clinic, dietary clinic, cardiology clinic, and orthopedic clinic. We also do minor, general, and dental surgery. When we receive a patient that we don't have the staff or technology to help, we fly them out to the nearest hospital, about 95 miles to the north in Rapid City.



Lt. Chris Charles is second from the right.

What do you love best about your job with the IHS?

I love the variety of areas and specialties I get to work in. Because we have so many clinics and different areas like acute and primary care, I get to work with the providers on those teams collaboratively. For example, the outpatient clinic is more clinical than a traditional community chain pharmacy. At big chain pharmacies, all we have is the patient's prescription, but here, I have the full EHR (electronic health record). We are expected to look at drugs more closely and call the doctor based on the patient's disease state, other medications, allergies, labs, etc. We access all of that before we fill the prescription. That gives us the opportunity to better serve the patient.

There is also a lot of opportunity for involvement with other professions. I have been able to give in-service presentations to the nursing staff. We have a cafeteria that everyone loves to eat in and we basically all eat together. It gives a chance to build relationships and rapport with the whole healthcare team.

There is also opportunity to be involved with the Corps, even though you are stationed in a remote area. I still get email from the Corps PharmPac and Commissioned Officers Association (COA). They have a lot of opportunities to get involved, develop yourself, and take on leadership positions. I am currently the APhA House of Delegates alternate delegate for the Corps, and Treasurer for the local COA branch.

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Student Pharmacists' Developments with the Maryland Pharmacists Association

By Lee J, Dieso P, Vepuri D, Aung L, Nguyen V.

There is no denying that the profession of pharmacy is undergoing a rapid evolution, as there have been significant advancements in pharmacists' roles and professional responsibilities. Due to the continuous changes in the professional landscape, it is vital for student pharmacists — the incoming generation of pharmacists — to be engaged in the discussions and practices regarding the profession's directions. Within the Maryland Pharmacists Association (MPhA), a commitment to the future is evident as student pharmacists are given a seat at the table (both literally and figuratively) when it comes to discussing challenges and solutions to these challenges.

With the president of the American Pharmacist Association — Academy of Student Pharmacists (APhA-ASP) from each Maryland school of pharmacy represented in MPhA, student pharmacists are playing an active role in their state association's decision-making to shape the profession. On a rotating basis, one of the student representatives serves as a voting member on the MPhA Board of Trustees. These opportunities are unique and rewarding as echoed by this year's ASP representative, Patricia Dieso from the Notre Dame of Maryland University. According to Dieso, "being an ASP student representative for MPhA this semester has shown me how involved pharmacists are with evolving their roles in pharmacy. At many meetings, we have discussed supporting pilot runs of changes to help improve a pharmacist's work load to give them more patient interaction. It's great to be a part of this as the roles of pharmacists are always changing." Student involvement extends beyond APhA-ASP representatives as well, as numerous student pharmacists serve on various committees. Some activities over the past few years have included helping plan/create events, creating advertisement material, and even having one member, Andrew Wherley, serve as the technician network co-chair. Wherley states, "As the technician network co-chair I've had the opportunity to work with a lot of different members to provide a voice for technicians at MPhA. Being trusted with this responsibility as a student has helped me improve many of my communication skills. It truly goes to show how much emphasis the MPhA members place on educating and mentoring the next generation of pharmacists."

— Andrew Wherley

Students attend a poster presentation from a student-peer on his research conducted at the Notre Dame of Maryland University.

Students from all three pharmacy schools in Maryland attend the inaugural Spring Into Your Career event, co-hosted by MPhA, NDMU, UMSOP, and UMES.

lot of different members to provide a voice for technicians at MPhA. Being trusted with this responsibility as a student has helped me improve many of my communication skills. It truly goes to show how much emphasis the MPhA members place on educating and mentoring the next generation of pharmacists." Through the different roles that student pharmacists serve in MPhA, the common theme amongst students is the impact that their actions hold in directing the trajectory of pharmacy careers.

MPhA also emphasizes student growth through the Professional Development Committee. Chaired by two University of Maryland School of Pharmacy alumni, Virginia Nguyen and Lynn Aung, the Professional Development Committee supports student initiatives and brings programming events to the pharmacy schools in Maryland. In just the past two years, the Professionalism Development Committee has overseen numerous initiatives such as the first MPhA pharmacist roundtable event and the first ever collaborative event involving all three Maryland schools of pharmacy: Spring Into Your Career. Within the past year, Maryland student pharmacists listened to topic discussions from two distinguished pharmacists, participated in a networking roundtable event, and engaged in a student poster presentation session. The concept of collaborative programming continued beyond the event, as the 2017 Fall saw another program developed by all three schools, Clinical Aspects of Medical Marijuana, presented by guest speaker Dr. Kari Franson. The students' benefits from MPhA's focus on their development have been unlike any previous years. Co-chair Virginia Nguyen states, "as new practitioners, we vividly remember how overwhelming it can be to navigate through pharmacy school and develop clinical and professional skills. What we wanted to do with the Professional Development Committee is help students prepare for a constantly changing pharmacy landscape. Through our roundtables or professionalism forums, we wanted to ensure that each student goes from 'sitting on the sidelines' to becoming better stewards of their profession and practice." Without a doubt, the sustained development of programming, partnerships, and relationships amongst the schools in Maryland is a testament to the Professional Development Committee's dedication to fostering student growth.

As the pharmacists' role advances, student pharmacists are able to actively support their fellow classmates by providing these various opportunities and more by having an active role through MPhA. These opportunities are what help shape the careers of our future pharmacists and provide them with new and evolving information they may need to advance their careers.

Professional Development Committee Chair, Virginia Nguyen, greets a student pharmacist prior to the first MPhA pharmacist roundtable event.

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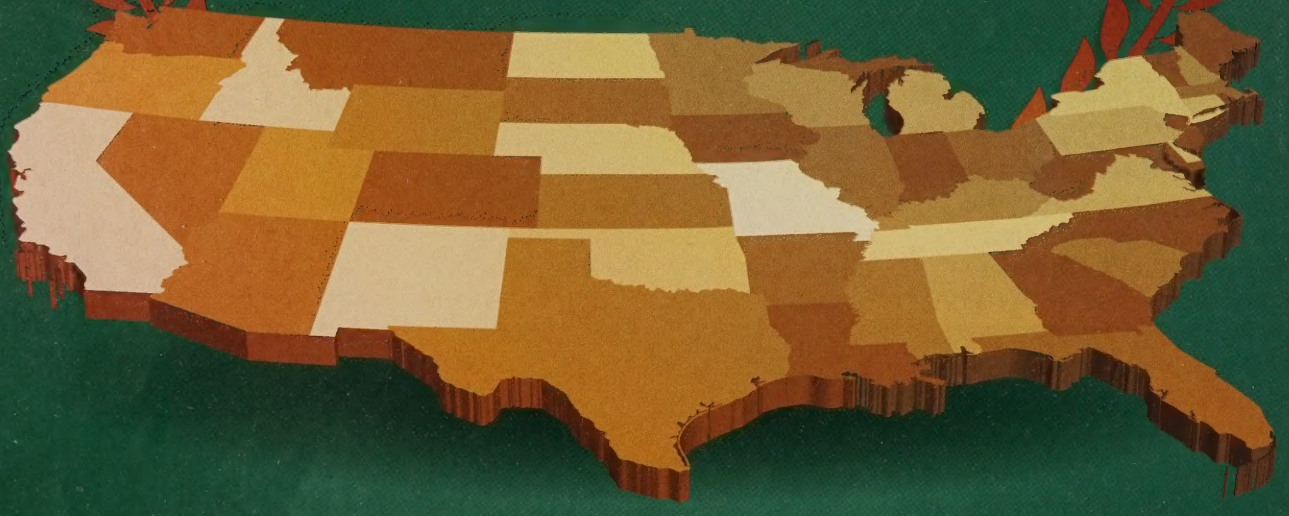

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Continuing Ed

Vaccine Recommendations for HIV-Infected Individuals

By Sumit Gandotra, PharmD Candidate 2019, Neha S. Pandit, PharmD, AAHIVP, BCPS

Learning Objectives

After completion of this activity, the participants will be able to:

1. Discuss how HIV infection affects the efficacy and safety of vaccinations
2. State current ACIP guidelines for vaccination in HIV-infected individuals

Keywords
CD4 count
HIV
vaccination

Introduction

Human Immunodeficiency Virus (HIV) attacks and depletes CD4 cells, compromising both cell-mediated and humoral immunity. Untreated HIV can progress to Acquired Immunodeficiency Syndrome (AIDS) defined as a CD4 count <200 cells/mm^3, leading to an increased risk of infections. Vaccinations can help ease this burden. However, as vaccine efficacy is highly dependent on a functioning immune system, a reduced antibody response may be seen as the CD4 counts decline. Vaccines contain either living material that is significantly weakened (live vaccines) or inactive material important in causing an infection but unable to do so on its own (inactivated vaccines). At low CD4 counts there is a risk of live vaccines causing active infections, therefore only administration of inactivated vaccines are recommended in the HIV-infected population[1]

Despite the widespread knowledge of the risks associated with preventable diseases, the rates of vaccinations in the HIV-infected population leaves something to be desired. The Advisory Committee on Immunization Practices (ACIP) outlines recommended vaccinations for HIV-infected patients [Table 1].[2] Studies have shown vaccination rates of 50% for >3 doses of hepatitis B vaccine, 40% for annual flu vaccine, and 30% for meningococcal or tetanus, diphtheria, and acellular pertussis (Tdap) vaccines in eligible HIV-infected patients.[3,4,5] Some studies have identified mild adverse events (AEs) to inactivated vaccines and increased AEs to live vaccines in the HIV-infected population.[1] It is clear that the overall rate of vaccination among the HIV-infected population is very low.

The lack of knowledge regarding vaccine eligibility, efficacy and safety differences, and the consistently evolving ACIP guidelines may be contributing factors to the low rates of adherence to best immunization practices in this population. This article aims to review the available information on the efficacy and safety of vaccinations for the HIV-infected population.

Influenza

HIV-infected and uninfected individuals are equally at risk for contracting influenza. However, the severity of illness may be increased in the HIV population, leading to higher rates of hospitalization, morbidity, and mortality.[6] Illness severity can be minimized with vaccination but the antibody response to vaccination is almost absent with CD4 counts ≤100 cells/mm^3 with no improvements seen with booster or increased dosages. Annual vaccination improves prevaccination antibody titers in HIV-infected patients with CD4 counts >300 cells/mm^3.[7]

ACIP recommends the use of annual trivalent inactivated influenza vaccine (IIV3) for those that are

Table 1: ACIP vaccination recommendations for HIV-infected adults[2]

Vaccination	Live or inactivated	CD4 >200 cells/mm^3 and/or CD4% ≥15%	CD4 <200 cells/mm^3 and or CD4% <15%
Influenza	Inactivated	✔	✔
Tdap	Inactivated	✔	✔
Pneumococcal	Inactivated	✔	✔
Meningococcal conjugate	Inactivated	✔	✔
Hepatitis B	Inactivated	✔	✔
HPV	Inactivated	✔	✔
MMR	Live	✔	
Varicella/Herpes	Live	✔	

≥6 months of age, regardless of CD4 count.[8] Data shows IIV3 to be 27–78% effective in preventing influenza in HIV-infected individuals with a CD4 count >100 cells/mm^3 compared to 11% in those with CD4 counts ≤100 cells/mm^3.[9,10] The safety of IIV3 in HIV-infected individuals was of concern after conflicting reports of increases in HIV RNA levels and decreases in CD4 counts after vaccine administration.[9] These results were found to be transient and lacked clinical significance.

There is limited efficacy data for the live attenuated influenza vaccine (LAIV) in the HIV-infected population. One study showed that children with a median CD4 count of 645 cells/mm^3 and HIV RNA of 20 copies/mL had similar immune responses compared to uninfected children given the LAIV.[11] Due to the limited data, ACIP continues to recommend against the use of LAIV in the HIV-infected population.

Meningitis

The incidence of invasive meningococcal infection (IMI) fluctuates from 0.5–1.5 cases per 100,000 population annually to 3.4–6.6 cases in the HIV-infected population.[12,13] The overall risk of IMI in HIV-infected patients continues to rise as CD4 counts decline and HIV RNA levels increase with the highest risk in patients with a CD4 count of <200 cells/mm^3.[13,16] Regardless of HIV status, the highest incidence of IMI is seen in the infant population.[12] With the increased incidence of IMI seen in the HIV-infected population, ACIP updated their recommendations to routinely vaccinate for meningococcal disease as of 2016.[13] Six serogroups (A, B, C, W-135, X, and Y) are responsible for most IMIs with B, C, W, and Y causing the majority of infections in the HIV-infected population within the United States.[1,13]

Currently two conjugated meningococcal vaccines exist against serotypes A, C, W, and Y (Menactra and Menveo). ACIP recommends that the primary series in HIV-infected individuals that are <2 years old receive a series of Menveo at ages 2, 4, 6, and 12–15 months. If the HIV-infected individual is ≥2 years old, both Menactra and Menveo can be given as a two series 8–12 weeks apart.[13]

The efficacy of the meningococcal vaccine is highly dependent on one's CD4 percentage (CD4%), yet, antibodies seem to diminish over time for HIV-infected individuals. The proportion of HIV-infected patients with an adequate amount of antibody titers to serogroup C decreased from 65% at 4 weeks to 21% at 72 weeks after one dose of MenACWY-D (Menactra) in those with a CD4% ≥15%. A similar decrease from 83% to 63% was seen for serogroup Y. With a 2nd dose of the vaccine given at 24 weeks to the same population, the proportion of patients with adequate titers went from 59% to 35% for serogroup C and 73% to 71% for serogroup Y, 4 weeks and 72 weeks post vaccination. For those with a CD4% <15 the overall response to the vaccine was decreased even with a 2nd dose. The proportion of patients with adequate titers in this population decreased from 22% to 6% for serogroup C and 30% to 28% in serogroup Y, four and 72 weeks post vaccination.[13] Due to the finding of diminishing antibodies over time in the HIV-infected population, a booster vaccination every 5 years is recommended [Table 2].[13-15]

Serious adverse events after meningococcal vaccine administration were seen in 2.2–6.5% of patients within six weeks of vaccine administration. The rates of these events are inversely related to CD4%.[13]

Tetanus, Diphtheria, and Pertussis

Due to vaccination efforts, from 2001–2008 the incidence of tetanus within the U.S. was 0.1 cases per million population annually; from 2004–2015 only two cases of diphtheria were reported; however, in 2015 over 20,000 cases of pertussis were reported in the U.S.[17-19]

HIV-infected individuals had similar antibody responses to uninfected patients for tetanus, however a decline in tetanus titers over time was seen even in patients who were previously vaccinated.[16,20] A lower antibody response was seen to diphtheria after vaccination, especially with CD4 counts <300 cells/mm^3.[16,21] A similar decline in pertussis antibody concentrations was seen 24 weeks post booster vaccination in children with a CD4% ≥15% with a minimal response seen in CD4% <15%.[22] The diminished protection to tetanus, diphtheria, and pertussis lead to the belief that booster vaccinations may be necessary sooner than every 10 years for HIV-infected patients, though more frequent boosters are not currently recommended by ACIP [Table 3].[20]

Diphtheria, tetanus, and pertussis vaccinations (DTaP) are made with inactivated material. Adverse events associated with DTaP were similar between vaccinated and unvaccinated HIV-infected children with the most common events mostly attributed to the patients' antiretroviral therapy.[20] There is limited data on Tdap in HIV-infected individuals, however, results are suggestive to be similar to DTaP.[16]

Pneumococcal Diseaseonia

Between 1996–2011, the burden of invasive pneumococcal disease (IPD) in adult HIV-infected individuals was 160 cases compared to eight cases per 100,000 person-years in uninfected individuals.[23] Recurrence,

Table 2: Meningococcal Vaccines in HIV-infected individuals and their Dosage, Administration, and Schedule[13-15]					
Name	**Dose**	**Site**	**Age**	**Schedule**	**Booster**
Menactra	0.5 mL	IM	Age 55 years old	Two-dose series given 12 weeks apart	• If <7 years from previous series: Give additional dose 3 years after primary series; boosters every 5 years thereafter • If ≥7 years from previous series: Give additional dose 5 years after primary series; boosters every 5 years thereafter
Menveo*	0.5 mL	IM	2 months	Four-dose series at 2, 4, 6, and 12–15 months of age.	
			7–23 months	Two-dose series with the second dose administered in the second year of life and at least three months after the first dose	
			2–55 years old	Two-dose series given 8–12 weeks apart	
Menomune	0.5 mL	SQ	≥56	Single Dose	

**It is important to note that Menveo is supplied in two separate vials that must be reconstituted before administration*

Table 3: Tetanus, Diphtheria, and Pertussis vaccinations for HIV-infected individuals[20]				
Name	**Dose**	**Site**	**Age**	**Schedule**
DTaP	0.5mL	IM	6 weeks–6 years	5 dose series: age 2, 4, 6 months then at 15–18 months and then at 4–6 years
Tdap			7–10 years (if not fully vaccinated)	Single dose
Tdap[a]			≥11 years (if no record of vaccination)	Single dose
Td				Every 10 years

[a]Pregnant women—Single dose during 3rd trimester for each pregnancy

morbidity, and mortality of IPD is more common in HIV-infected individuals, however antiretroviral therapy (ART) has shown to minimize the incidence of IPD.[24]

The inactivated conjugate (PCV13) vaccine provided protective antibody response to HIV-infected individuals with a CD4 count ≥200 cells/mm^3 who had prior vaccination with the pneumococcal polysaccharide vaccine (PPSV23).[25] Moreover, a recent study indicated that HIV-infected adults with CD4 count ≥200 who never received a pneumococcal vaccination had higher antibody protection at weeks 8 and 28 from PCV13 followed by PPSV23 over PPSV23 alone. Similar studies have also shown that delaying the PPSV23 until six months after antiretroviral medication initiation did not improve immune response.[26]

For those naïve to pneumococcal vaccination, ACIP recommends PCV13 at time of HIV diagnosis regardless of CD4 count followed by PPSV23 vaccination ≥8 weeks later. A second PPSV23 dose can be given after five years if the HIV-infected individual is ≤65 years old. The third and final dose of PPSV23 can be given either at 65 years old or after five years from prior PPSV23 vaccination. If a patient has already received PPSV23, PCV13 should be administered ≥1 year later with a repeat of PPSV23 after five years. If the patient is not yet 65, they can receive one final PPSV23 vaccination at 65 years old or after five years from the 2nd dose of PPSV23.[27] HIV-infected individuals with CD4 counts of <200 cells/mm^3 can defer receiving PPSV23 until their count rises above 200.[25] PCV13 and PPSV23 have been deemed safe for use in the HIV-infected population.[24]

Hepatitis B Virus

It is estimated that close to 40% of HIV infected patients are also co-infected with hepatitis B virus (HBV), with the incidence of chronic HBV infection close to 10%.[28] One study has shown that 15% of deaths in HIV-infected adults can be attributed to liver disease.[29] HBV is a common cause of liver disease and it is well known that AIDS leads to faster progression to hepatocellular carcinoma.[30]

HBV vaccination differs in effectiveness when given to HIV-infected individuals (18–68% effective) as opposed to uninfected individuals (60–95% effective).[16] Completing the HBV vaccination series before contracting HIV confers similar protection against HBV as in HIV-uninfected individuals.

Therefore, it is optimal to begin HBV vaccination before or at the time of HIV diagnosis.[16] If a delay occurs, duration of protection is decreased in HIV-infected individuals, declining to 70% protection after 12 months to 30% after 24 months.[30] For HIV-infected individuals who fail to seroconvert (<10 mIU/mL) after receiving all immunizations within a series, double-dose (40µg) HBV vaccination have been proposed as follow-up. Seroconversion rates have been reported at 51–77% with better response in those who are taking combination ART and have higher CD4 counts (≥350 cells/mm_3).[16] Furthermore, double-dose immunizations may confer durability. At 72 weeks post-vaccination, 56% of those who received a single dose immunization lost response whereas only 23% lost response in the double-dose group.[31] [Table 4] provides further information.[32,33]

The HBV vaccination series is well tolerated in both single and double-dose trials with local reactions being more prevalent in double-dose immunizations.[31] The HBV vaccination series has received endorsement from the WHO Global Advisory Committee on Vaccine Safety (GACVS).[30]

Human Papillomavirus

Human Papillmoavirus (HPV) is the most common sexually transmitted disease with an estimated prevalence of 45% in the general population and rates as high as 73% in the HIV-infected population.[16,34] HIV-infected patients with HPV also have a higher incidence of infections with oncogenic serotypes also known as high-risk HPV (HR-HPV).[16] Despite the increased prevalence, it is estimated that only 17.2% of men who have sex with men, aged 18–26 years, receive ≥1 HPV vaccination.[35]

There is limited data on the inactivated vaccine Gardasil-9 and its immunogenicity and safety in HIV-infected individuals. ACIP, however, recommends Gardasil-9 for HIV-infected individuals regardless of CD4 count, advising a three dose series (0, 1-2, and 6 months) for females and males between the ages of 9–26.[36] If an individual has HPV, they should still receive the vaccine to prevent against infection with other oncogenic HPV serotypes.[16]

Table 4: HBV vaccine administration, dosing and schedule for Recombivax HB and Engerix-B in HIV-infected individuals[32,33]

Name	Dose	Site	Age	Schedule
Recombivax	0.5mL	IM	Birth–19 years	0, 6 months
Engerix	0.5mL			
Recombivax	1.0 mL		11–15 years[a]	0 and then 4–6 months
Recombivax	1.0 mL		≥20 years	0, 1, and 6 months
Engerix	1.0 mL			

[a]*Adolescents can receive either two or three dose series*

Measles, Mumps, Rubella

The incidence of measles, mumps, and rubella (MMR) in the general population is low due to continued vaccination efforts. In 2014, the number of new cases per 100,000 population were 0.21, 0.38, and 0, respectively.[37] Early studies have shown that mortality rate for HIV-infected patients with measles is as high as 40%, however a lower rate was seen in those that were vaccinated.[38]

A cross-sectional analysis assessed the humoral immune response to a measles vaccine between HIV-infected and uninfected individuals. There were no differences three months after vaccination. However, at one year 34% of the HIV infected patients remained seropositive compared to 80% in the uninfected population. This same study also assessed adaptive immune response to measles which included a positive IgG measles ELISA and/or a positive cellular proliferative response after vaccination. The results did not find any difference between the two groups 12 months after vaccine administration.[39]

All three of these organisms are administered as one live vaccine. Due to the risk of measles pneumonitis after MMR vaccination, HIV-infected individuals are only eligible for this vaccine once their CD4 count is ≥200 cells/mm^3 or ≥15%.[16] Safety data suggests the MMR vaccine is well-tolerated in children and adults.[40,41] Reports have shown transient increases in HIV-1 RNA levels with a return to baseline 6–8 weeks after MMR vaccination but the long-term consequences of this increase is unknown.[42]

Varicella and Herpes Zoster

Varicella zoster virus (VZV) is the etiological cause of chickenpox whereas the herpes zoster virus (HZV) is a reactivation of latent VZV. VZV infection in HIV-infected individuals can increase HIV viral loads.[43] HZV has a higher prevalence in the elderly population but is also 10–30 times more likely in HIV-infected patients, regardless of age.[44] In the general population, the VZV vaccine is recommended for children starting at 12 months of age whereas the HZV vaccine is recommended in those ≥60 years of age.[45]

VZV vaccine efficacy in HIV-infected children, 1–8 years old, had antibody responses of 59%–72% at 20 weeks of vaccine series completion, which declined to 43%–65% one year after.[43] In contrast, VZV vaccine efficacy in healthy children is >85%.[46] VZV vaccine has been shown to be well tolerated with local injection site reactions being the most noted.[43] Nevertheless, HIV-infected individuals are at a higher risk for developing complications including pneumonia and encephalitis and are subsequently associated with a 25-fold higher risk of death. Therefore, a series separated by ≥3 months and a CD4 count of ≥200 cells/mm^3 is recommended for those that lack immunity.[47]

HZV, however, is an endogenous infection for persons that have been exposed to VZV primary infection. HZV vaccine, therefore, must act to alter the host-virus relationship by boosting immunity in order to decrease illness severity.[48] The HZV vaccine contains 14 times the amount of VZV in it.[49] The effectiveness of this vaccine was close to 37% in the immunocompromised patient population, but this was not specifically looking at HIV-infected patients. HZV is also administered as a single dose injected subcutaneously.[49] Protection declines precipitously after five years.[50] Data regarding the safety and efficacy of HZV vaccine in HIV-infected individuals is lacking. A study, evaluating 295 HIV-infected patients with a CD4 ≥200 cells/mm^3 found that HZV vaccine was safe and immunogenic in HIV-infected individuals but was not powered to evaluate efficacy.[51] A new HZV vaccine (Shingrix, GlaxoSmithKline) was approved by the FDA for use in adults >50 years in October 2017. There is limited data to date on the use of this new product in HIV-infected subjects. The vaccine is considered to be a non-live recombinant.[52]

Conclusion

In conclusion, the likelihood of vaccine efficacy within the HIV population is dependent upon a functioning immune system. For the most part, this is defined to be a CD4 count ≥200 cells/mm^3 and a CD4% ≥15%. It is recommended that vaccines be administered as early as possible, especially if the vaccines are live. Inactivated vaccines, however, have been shown to be effective with lower CD4 counts and can thus be given at any time. It should be noted that inactivated vaccines are not devoid of adverse effects and that caution should be taken during all vaccine administrations. Finally, in instances such as PPSV23, vaccination can be delayed until the CD4 count rebounds to above 200 for optimal efficacy.

Patient Case:

HM is an 18-year-old CM that has come to the pharmacy to pick up his prescription. He has agreed to get the influenza shot but has questions about other immunizations he needs before he starts college. After getting his medical history, you find out that HM has been HIV-infected for the past year. He is adherent to his medications and has claimed that his last viral load was determined to be undetectable. Additionally, his last reported CD4 count was 300 cells/mm^3. He has received his MMR, Tdap, and Varicella vaccines in the past. When asked about allergies, HM noted that he had trouble moving his arm last time he received the influenza vaccine.

Case Questions:

1. If Menactra is supplied in your pharmacy, how would you schedule HM's doses(s)?

a. Single dose

b. Two doses spaced 10 weeks apart

c. Four dose series

d. HM is not indicated for Menactra since his CD4 cell count is too low

2. What other vaccinations is HM indicated for?

a. Pneumococcal

b. Hepatitis B

c. A &B

d. None of the above

3. HM wants to receive the HPV vaccine. What can you tell him?

a. HPV vaccine is not recommended for males

b. He is too young to receive the vaccination

c. He can receive the vaccine as long as his CD4 count is above 200 cells/mm^3

d. He can receive the vaccine regardless of CD4 count

Answers on page 16

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ANSWERS

1. Answer: B

For HIV-infected individuals who are between the ages of 2–55 years old, Menactra is recommended as a two-dose series given 12 weeks apart. Menactra is an inactivated polysaccharide vaccine that is recommend for HIV-infected patients regardless of current CD4 count.

2. Answer: C

HM is an 18-year-old Caucasian male that is HIV positive. He is indicated to receive both Pneumococcal and Hepatitis B vaccinations.

3. Answer: D

HPV is an inactivated vaccination that is recommended to boys and girls ages 9–26. Therefore, he can receive the vaccine regardless of CD4 count.

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Interview: Lieutenant Chris Charles *continued from page 6*

How is practicing within the Indian Health Service different from other experiences that you have had?

The main thing is the variety of areas I get to work in. I'm not only the outpatient pharmacist, I'm also the inpatient and clinic pharmacist. I have a broad scope of practice here. I also enjoy full access to patients' EHRs.

What is your day-to-day responsibility?

The pharmacy team starts the day by making sure that the ScriptPro is working. We do about 1,200-1,400 prescriptions a day, so ScriptPro has to be working. We run the refill list and start to process the prescriptions. As the processing pharmacist, we will park ourselves at the computer because most of our scripts come through electronically from the clinics. We check them for interactions, look through the patient EHR, screen for immunizations, and call the doctors as needed. As the filling pharmacist, I'm at the back with the ScriptPro, making sure that it is stocked with bottles, filling prescriptions, and listening to Chinese on my headphones because I'm learning Chinese. As the clinic pharmacist, I jump right in: I counsel patients, provide recommendations to the providers, and review labs. As the narcotics pharmacist, I focus our day on narcotics stewardship work — we handle all the narcotics for the hospital. Lastly, as the acute care pharmacist I manage all the pharmaceutical needs and many of the clinical needs of our patients admitted to the inpatient ward.

What tips would you give to anyone who is interested in joining the Indian Health Service?

- The very first thing would to decide whether you want to be Corps or civilian because to work for the IHS, you don't have to be Corps. You still qualify for loan repayment as a civilian.
- Be open-minded as to where you want to go.
- Get a good pair of hiking boots because you will be out and about.
- Visit the site, if you can, or at least talk to people that work there. Every site is different.
- Lastly, get ready for adventure.
- For students — pass your boards and get your license!

What do you miss about being in Maryland?

I miss my friends. I miss the MPhA family. And I miss the variety of restaurants in Baltimore. I miss the short commute. There is beautiful scenery here, but the drive can be a bit drawn out. And it is cold here! We have seen temperatures below 10 degrees already (late October) and several flurries. ●

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Editorial

Maryland Pharmacist's Role in Preventing and Treating Sexually Transmitted Infections

By Elisabeth Liebow, MPH, Policy and Program Associate Center for STI Prevention, Maryland Department of Health

Maryland pharmacists can play a critical role in addressing the significant public health burden of sexually transmitted infections through an intervention known as Expedited Partner Therapy (EPT). EPT is the voluntary clinical practice of treating the sex partners of patients diagnosed with certain sexually transmitted infections (STIs), without an intervening medical examination of the partners. EPT has been shown to decrease the likelihood of repeat infection in the index patient. The Centers for Disease Control and Prevention (CDC) recommends EPT as a useful chlamydia and gonorrhea treatment option for heterosexual partners who are unlikely or unable to obtain timely testing, counseling and treatment.[1,2] The CDC also encourages consideration of EPT for partner treatment of trichomoniasis.[2] Numerous national organizations endorse the practice. In Maryland, the Maryland Pharmacists Association, along with all major chapters of medical societies and the medical boards, endorse EPT.

Burden of STIs in Maryland

Rates of chlamydia and gonorrhea are at record high levels nationally and have risen significantly in Maryland.[3,4] From 2015 to 2016, reported cases of chlamydia in Maryland increased 11.6%. In 2016, there were 30,658 cases reported, a rate of 510.4 per 100,000 population. Reported cases of gonorrhea rose an alarming 38.9% from 2015 to 2016. There were 9,523 cases of gonorrhea reported in 2016, a rate of 158.5 per 100,000 population. While preliminary 2017 year-end data indicate the dramatic increase appears to have slowed, increases are still occurring (unpublished surveillance data, Maryland Department of Health). The CDC estimates that trichomoniasis is the most prevalent non-viral STI nationwide, though the true burden of disease cannot be measured since trichomoniasis is not a reportable disease.[2] Like chlamydia and gonorrhea, untreated trichomoniasis can cause severe sequelae, especially in females, including pelvic inflammatory disease, infertility and ectopic pregnancy.

EPT in Maryland

In Maryland, EPT can legally be prescribed and dispensed for partner treatment of chlamydia and gonorrhea as of June 1, 2015, and trichomoniasis as of October 1, 2017.[5] Pharmacists are authorized to dispense EPT as prescribed. See Maryland Health-General, Code Ann. § 18-214.1 (2017)5. For practitioners and pharmacists implementing EPT, Maryland law and implementation regulations specify the following:[5,6]

- All EPT prescriptions must include the designation "Expedited Partner Therapy" or "EPT;"
- Separate EPT prescriptions must be issued for each partner;
- If a sex partner's name is unknown, the written designation "EPT" is sufficient for the pharmacist to fill the prescription.

By the Numbers

STIs in Maryland

11.6%
Percent of increase in reported chlamydia cases from 2015 to 2016

30,658
Amount of chlamydia cases reported in 2016

510.4
Rate per 100,000 of chlamydia cases reported in 2016

38.9%
Percent of increase in reported gonorrhea cases from 2015 to 2016

9,523
Amount of cases of gonorrhea reported in 2016

158.5
Rate per 100,000 of gonorrhea cases reported in 2016

Though not required, this information can be obtained when the patient or partner drops off or picks up the partner's prescription;

- EPT prescriptions may not be refilled;
- Pharmacists (and prescribers) must provide written informational materials to patients and each partner. The accompanying information must include advice for the partner to seek medical care even after taking EPT; information about the infection; medication instructions; warnings about allergic reactions; and advice to abstain from sex for seven days post-treatment.
- Chlamydia and gonorrhea informational materials for patients and partners are available for downloading on the Maryland Department of Health's EPT web site at http://bit.ly/EPTMaryland. New materials for trichomoniasis are in production and will be available shortly. Alternatively, comparable educational materials may be used.

EPT Treatment Regimens for Partners

- Chlamydia treatment delivered via EPT — 1 gm azithromycin orally once.
- Gonorrhea treatment delivered via EPT — dual oral treatment with 400 mg cefixime once PLUS 1 gm azithromycin once.
  - *Note: Due to the emergence of resistance to oral cephalosporins, the CDC-recommended in-office treatment of gonorrhea is 250 mg ceftriaxone once IM PLUS 1 gm azithromycin orally once.*
- Trichomoniasis treatment delivered via EPT — 2 gm metronidazole orally once OR 2 gm tinidazole orally once.

Operationalizing EPT

- Paying for EPT: (1) If the partner's name is on the prescription, the medication may be paid for out of pocket by the person picking up the prescription (the patient or the partner), or by the partner's health insurance. (2) If a prescription is issued to "EPT" with no partner name included, the medication must be paid for out of pocket, or the unnamed partner wishing to have his insurance cover medication costs must provide identification to the pharmacist. Pharmacists should not bill the partner's prescription to the index patient's insurance.
- Creating profiles for unnamed partners: Patients most often know and disclose sex partners' names to their clinicians. And, pharmacists have an additional opportunity to ask for the partner's name for those prescriptions simply issued to "EPT." Unnamed prescriptions, though legally permissible, pose challenges.
  - Consider creating a patient profile called "EPT Partner." If your computer system requires additional patient demographic information, use your professional judgment as to what makes sense, such as creating a unique identifier and a default birthdate.
  - Alternatively, consider designating a sequential numeric identifier as the first name on each unnamed prescription, "EPT" as the last name on each, and a default birthdate, resulting in numerically identifiable prescriptions for unnamed partners. First unnamed prescription: 001 (first name), EPT (last name), 01/01/2000 (DOB); the next unnamed EPT prescription would be 002 (first name), EPT (last name), 01/01/2000 (DOB); etc.
  - Consider assigning "EPT" to your Facility field for tracking all EPT prescriptions.

Adverse Events

Among 41 states in which EPT is legally permissible, there have been no known reported instances of serious allergic reactions to EPT, nor any lawsuits known to have arisen from the provision of EPT. Notably, California, the first state to authorize EPT (in 2001), received no calls to its toll-free EPT adverse events hotline. In Maryland, patients and partners with concerns about serious allergic reactions to EPT are advised to contact the Maryland Department of Health at 410-767-6690.

Resources

In addition to fact sheets, Maryland's EPT law, implementation regulations and provider guidance can be found on the EPT website. Additional EPT information can be found at: https://www.cdc.gov/std/ept/default.htm.

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And a Good Time Was Had by All!

Thank You to the 2017 MPhA Foundation Donors

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Executive Director's Message

Happy New Year! As we kick off 2018, I wish you a year full of meaning, happiness and prosperity!

For those of you new to MPhA ... Welcome!

The MPhA Board of Trustees, committee leaders and its members are committed to you. We continually work to shine a light on you, so that the public knows the contributions you make in enhancing patient access to health care and improved patient outcomes.

We continue to work toward achieving the goals of our strategic plan, with an emphasis on membership value, recruitment and retention.

A critical area identified in the strategic plan is advocacy. This time of year, includes the kickoff of the 2018 legislative session in Annapolis. Your support of MPhA provides resources for that advocacy. At the forefront are our efforts to advance the profession and to protect sectors within our community that come under assault. Over the last few years, we have generated significant recognition in Annapolis. This has been an investment of time and resources of leadership, staff and members.

The 2018 session is looking to be another barnburner, with bills focused on pharmacy reimbursements, MAC pricing, PBM issues and prescription drug pricing. Our Advocacy Committee is finalizing details related to pursing legislation to expand pharmacists' medication administration. As members of the General Assembly look to address the opioid epidemic and revise the oversight of the production and dispensing of medicinal cannabis, we will support efforts that maintain the pharmacist's ability to assist in achieving positive outcomes for patients, and will fight against any unfunded mandates and exclusion of pharmacists from providing medication expertise.

Please be ready to make calls, send emails and provide testimony. Your support will be needed.

As we focus on membership recruitment and retention, we are hosting focus groups and reaching out to segments of our community to determine how we can better serve your needs. These efforts will result in more focused investment of MPhA's resources.

Thank you again for you membership. I look forward to seeing you at the MidYear Meeting on February 18 and at Legislative Day on February 20. Please feel free to reach out to me with your ideas and suggestions at 443-583-8000 or aliyah.horton@mdpha.com. ●

Aliyah N. Horton, CAE
Executive Director

A critical area identified in the strategic plan is advocacy. Your support of MPhA provides resources for that advocacy. At the forefront are our efforts to advance the profession and to protect sectors within our community that come under assault. Thank you again for your membership.

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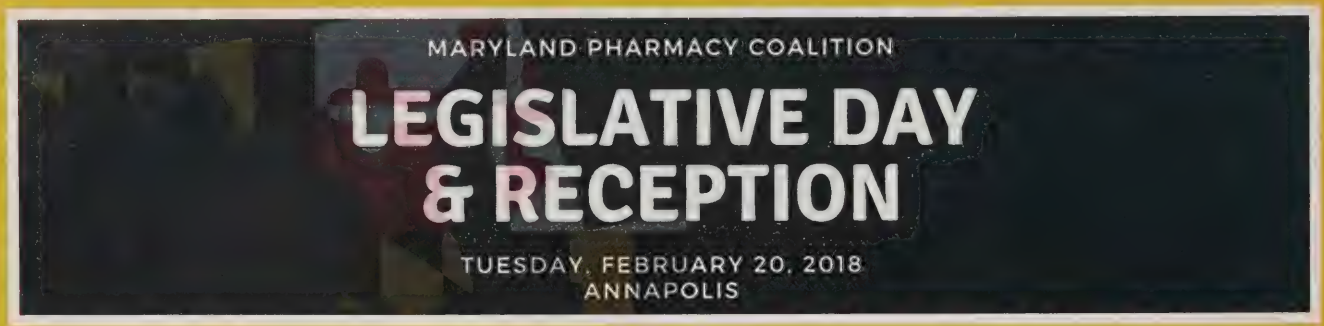

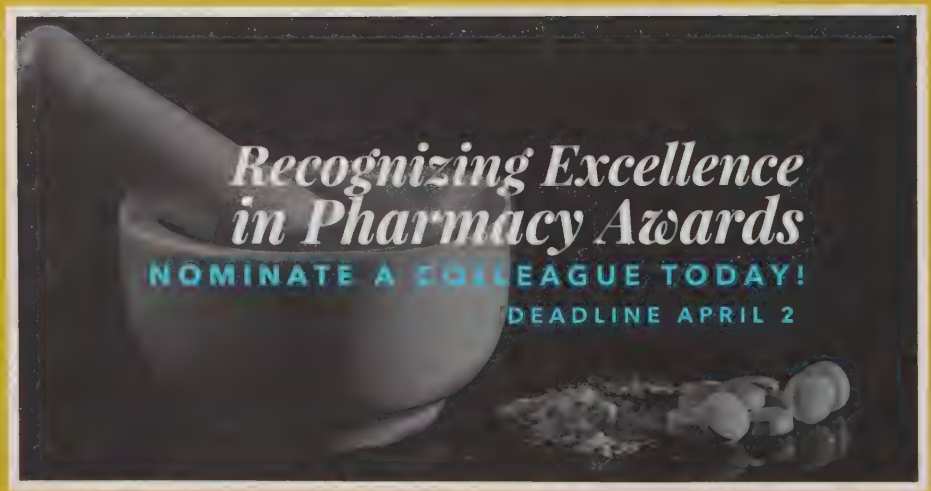

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2018 Legislative Session Recap

Mid-Year Meeting
Thank you to all who attended!

MPhA News
The Role of Professional Pharmacy Organizations and Its Impact on the Profession of Pharmacy.

Continuing Education
Falls Prevention in Older Adults

Maryland Pharmacist

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CONTRIBUTORS
NASPA Services Company, LLC, Editorial
Katy Pincus, PharmD, BCPS
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President's Pad

Congratulations to our soon-to-be graduates ... MPhA is an important resource for you as you continue your professional development after graduation.

Dear MPhA Members:

When we last saw each other, we were on the brink of Maryland Pharmacy Coalition's Legislative Day and as I write this, the 2018 legislative season has come to an end — but there is still work to be done to advocate for the profession.

Nothing is more inspiring than seeing pharmacists and student pharmacists from across the state descending upon Annapolis to help our legislators learn about pharmacy related issues. The excitement is palpable as participants make their way to the legislative visits to meet with delegates and their aides. There is no doubt that we left an indelible mark with our delegates and amongst each other who participated that day. Thank you to all the MPhA members who came to Legislative Day, as well as those who helped plan and contributed long hours to make the event a success. We are so fortunate to have a dedicated membership that volunteers so much of their time to support pharmacy — that is one of the great things I love about being a member of MPhA!

As I mentioned in the Winter journal, advocacy is a year-round activity. **Take the time to share your story about how you impact your community and your patients.**

Just a few weeks ago was the APhA 2018 Annual Meeting in Nashville, TN. We had an amazing number of MPhA members in attendance and the Maryland Pharmacy Night on Saturday night was also a hit. It was great to catch up with our Maryland pharmacy colleagues and enjoy each other's company. I know that many of us returned home from the meeting inspired, with many new ideas to implement in our practices.

Spring is finally here, and we're getting ready for the MPhA 136th Annual Convention in Ocean City, MD from June 29–July 2! The Meetings Planning Committee and MPhA staff are hard at work to bring you an amazing group of speakers to learn about different topics, earn continuing education credits, make new connections, and enjoy the beach. It's another fantastic opportunity to prepare you to be #ProviderReady! I can't wait to see everyone there.

Be sure to follow us on Facebook and Twitter, and check your inbox for the Monday Message to stay up to date with all MPhA events and any pharmacy-related news and updates.

As we round out the spring, it is time for our soon-to-be graduates to finish out their training and join the ranks as pharmacists. Congratulations to you on this hard-fought journey of pharmacy school. Know that we're rooting for you and are excited to see what you'll accomplish in practice. MPhA is an important resource for you as you continue your professional development after graduation — you are an important part of our membership and our work will continue with your support! We look forward to seeing you at MPhA events and New Practitioner activities. Congratulations to the Class of 2018!

Kindest regards,

Cherokee Layson-Wolf
President

Member Mentions & News You Can Use

Maryland at APhA2018

It was great to see so many Maryland pharmacists, technicians, and students in Nashville at the APhA Annual Meeting!

Special thank you to the hardworking MPhA members representing Maryland in the APhA2018 House of Delegates! Thank you for your service!

Award Recognition
Congratulations to the following MPhA members who were recognized with awards during the meeting:

- **Tolani Adebanjo** — APhA Foundation Boyle Family Scholarship
- **Jim Bresette** — Phi Lambda Sigma Advisor of the Year
- **Cynthia Boyle** — Phi Lambda Sigma National Leadership Award
- **Brian Hose** — APhA-APPM Immunizing Pharmacists Special Interest Group award
- **Cherokee Layson-Wolf** — APhA-APPM Immunizing Pharmacists Special Interest Group award
- **Joey Mattingly** — Elected Speaker-Elect by the APhA House of Delegates
- **Ashley Moody** — APhA-APPM Immunizing Pharmacists Special Interest Group award
- **Magaly Rodriguez DeBittner** — Sworn in as APhA Trustee

Joey Mattingly

Magaly Rodriguez DeBittner

Maryland's 2018 APhA House of Delegates representatives

And Congratulations to MPhA Members on These Recent Appointments

CARE Pharmacies Cooperative recently named MPhA Past President **Christine Lee-Wilson** to it's 2018 Board of Directors. Lee-Wilson holds a Doctor of Pharmacy degree from St. Johns University, New York and currently owns Professional Pharmacy in Baltimore. Congratulations Christine!

Lincy Abraham, past MPhA rotation student, was selected to be the 2018–2019 National Association of Chain Drug Stores Foundation's Executive Fellow.

Dr. Yen Dang of the University of Maryland Eastern Shore School of Pharmacy was appointed to the Maryland statewide immunization commission for a 3-year term as the pharmacist member. Her term ends in 2020.

A New Member to the MPhA Phamily!

Congratulations to MPhA Board Chair Kristen Fink and husband Andrew Wherley who welcomed their third son Cole Alexander on Thursday, April 5.

MPhA Member as Panelist on Opioid Series

MPhA Member Dr. Thomas Cargiulo appeared as a subject matter expert panelist on Maryland Public Television's "America Addicted" program summarizing PBS News Hour's opioid epidemic series on February 9, 2018. Full video can be found on Maryland Public Television's website.

2017 Recipients of the "Bowl of Hygeia" Award

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Arizona

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Pierre Del Prato
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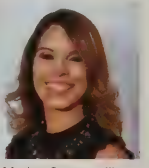
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Gary Kishfy
Rhode Island

Terry Blackmon
South Carolina

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Tennessee

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Kurt Price
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Wisconsin

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In Memoriam:

Rob Loe
South Dakota

Keith Campbell
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The Bowl of Hygeia award program was originally developed by the A. H. Robins Company to recognize pharmacists across the nation for outstanding service to their communities. Selected through their respective professional pharmacy associations, each of these dedicated individuals has made uniquely personal contributions to a strong, healthy community. We offer our congratulations and thanks for their high example. The American Pharmacists Association Foundation, the National Alliance of State Pharmacy Associations and the state pharmacy associations have assumed responsibility for continuing this prestigious recognition program. All former recipients are encouraged to maintain their linkage to the Bowl of Hygeia by emailing current contact information to awards@naspa.us. The Bowl of Hygeia is on display in the APhA History Hall located in Washington, DC.

Boehringer Ingelheim is proud to be the Premier Supporter of the Bowl of Hygeia program.

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  - Immunizations
  - Medication Therapy Management
  - New Drug Update
  - Job Burnout
  - Cardiovascular Benefits of Diabetes Medication
  - OTC Jeopardy
  - Opioids vs. NSAIDs Debate, and more
- Opportunities to network, connect, and re-connect with your peers
- Chances to gain new perspectives from our dynamic speakers
- Recognition of professional accomplishments
- Social activities all ages can enjoy
  - Crab Feast
  - Beach Games
  - Sunrise Yoga

Registration is open for MPhA's

136th Annual Convention

in Ocean City, MD! Pharmacists, pharmacy technicians, and student pharmacists from the surrounding regions convene, learn, network and engage with colleagues and peers at our biggest event of the year!

Look for Friday afternoon & Monday morning sessions!

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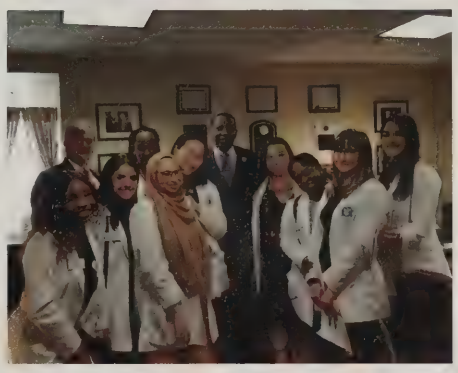
The Role of Professional Pharmacy Organizations and its Impact on the Profession of Pharmacy

By Enaefe Ziregbe, PharmD Candidate 2018, Howard University College of Pharmacy and MPhA Rotation Student



Pharmacy organizations have been heavily involved in shifting the focus of the pharmacy profession from traditional dispensing to pharmacists as an integral part of the health care team. The American Society of Hospital Pharmacists (ASHP) Hilton Head Conference in South Carolina in 1985 established the groundwork for pharmacy being recognized as a clinical profession. This conference led the ASHP Foundation to fund parallel state and regional programs leading to the widespread reexamination of the professional mission by hospital pharmacists and the creation of plans to transform their departments into clinical enterprises. The American Association of Colleges of Pharmacy (AACP) delegates in 1990 endorsed a paper that declared that the mission of pharmacy practice is to render pharmaceutical care.This was backed up by the American Pharmacists Association (APhA) in 1991 when it adopted a policy that stated "that the mission of pharmacy is to serve society as the profession responsible for the appropriate use of medications, devices and services to achieve optimal therapeutic outcomes." That same year, the ASHP House of Delegates voted unanimously to endorse the concept of pharmaceutical care. These examples from national pharmacy organizations show the importance and impact of pharmacy organizations in the practice of pharmacy.[1]

The Maryland Pharmacists Association (MPhA), established in 1882, has been pivotal in advancing the practice of pharmacy in the state of Maryland. MPhA is the only statewide professional society representing all practicing pharmacists and is affiliated with APhA, the National Community Pharmacists Association (NCPA), and the Academy of Managed Care Pharmacy (AMCP). The mission of MPhA is to strengthen the profession of pharmacy, advocate for all Maryland pharmacists and promote excellence in pharmacy practice.

MPhA has an umbrella organization, the Maryland Pharmacy Coalition (MPC), whose purpose is to provide a forum for discussion and understanding between Maryland's pharmacy associations on issues impacting the practice of pharmacy and public health. MPC strengthens relationships between pharmacy associations in the state and encourages collaborative efforts to benefit pharmacists and patients in Maryland. Members of the MPC include the Maryland Pharmacists Association, American Society of Consultant Pharmacists (Maryland chapter), Maryland Pharmaceutical Society, Maryland Society of Health System Pharmacists, University of Maryland Baltimore School of Pharmacy Student Government Association, University of Maryland Eastern Shore School of Pharmacy Student Government Association, and Notre Dame of Maryland University School of Pharmacy Student Government Association.[2]

Colleges of pharmacy vary in their educational offerings to students related to advocacy, and the annual MPC Legislative Day is an important day for pharmacists,

student pharmacists, and pharmacy technicians to join together to educate legislators and staff about the importance of pharmacy practice to the public health for the state of Maryland.[3] The most recent Legislative Day held on February 20, 2018 saw student pharmacists from University of Maryland, Notre Dame of Maryland University, and University of Maryland Eastern Shore Schools of Pharmacy come together to establish their stance on bills that had been introduced in the General Assembly. Students were divided into their various districts and spoke with their district delegates and senators on how these bills could positively or negatively affect the profession of pharmacy. For example, a Maryland house bill, HB601: Public Health – Opioids-Dispensing Requirement that was introduced required "a drug classified as an opioid to be dispensed with a nontoxic composition designed to permanently and chemically sequester or deactivate the drug and be used for disposal of the drug." The bill was opposed by MPC because it served as an unfunded mandate; was ambiguous regarding who would bear the cost and potentially legislated market share to the company advocating for the bill. Students spoke to the delegates regarding the cost concern since insurance companies were not obligated to pay for it. Students also informed delegates on the other options available for the disposal of opioids, like the National Prescription Drug Take-Back Day events, DEA-authorized collection sites, and pharmacies that have free on-site opioid disposal programs.

MPhA works with all pharmacists, regardless of practice area, to establish a stance on the bills proposed in the General Assembly and works with a lobbyist to facilitate getting its positions to the appropriate legislators. Written testimony supporting or opposing pharmacy-related bills are collected through MPhA and are presented to elected leaders on hearing days and as part of the ongoing advocacy process. Pharmacists who are interested in providing oral testimonies in support or opposition to a bill go through MPhA, who registers them to speak on hearing days. On March 8, 2018, there was a hearing on several bills that impacted independent pharmacies like HB1349: Pharmacy Benefits Managers-Revisions that affected Maximum Allowable Cost (MAC) lists, MAC appeals, and protection from retaliation among other issues related to PBMs. These issues have had a major impact on independent pharmacies in the past year and are causing some pharmacies to stop carrying certain medications due to below-cost reimbursement rates. A substantial number of pharmacists attended the hearing on this day to speak about their experiences with the unfair treatment by PBMs, who they believe reimburse PBM-owned pharmacies higher than independent pharmacies. Legislators heard the concerns raised by pharmacists during their testimony, and ultimately passed the bill with an effective date six months earlier than originally proposed.

It is important to recognize the chasm that would exist between pharmacists and lawmakers if MPhA was not present to help communicate the issues that pharmacists face while bills are being considered. MPhA helps lawmakers understand the impact that these bills have on pharmacists and provides pharmacists with a solid platform to express their issues.

The importance of pharmacy organizations in the advancement of the profession of pharmacy cannot be overemphasized. These organizations not only strengthen the profession of pharmacy, but also provide a unified voice for pharmacists to come together to brainstorm innovative ways to improve the current practices in place, while providing the best care for their patients. ●

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3. Maryland Pharmacist Association (MPhA) http://www.marylandpharmacist.org/ Date accessed: March 9th, 2018

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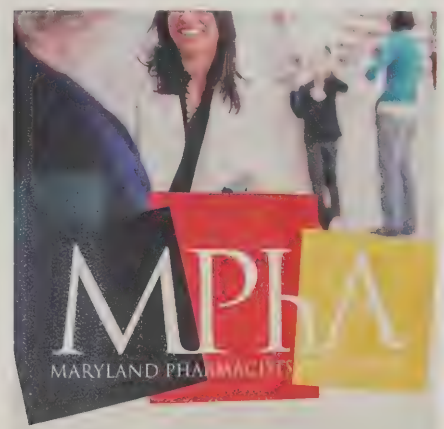
Kafi Agboola
Waheed Aziz
Tawfik Beshir
Michael Bochniewicz
Rajkamal Brahmanapalli
Melinda Burke
Chaitanya Chittimalla
Parnab De
Brittany Eisemann
Tanisha Gooden
Marcelle Gossan
Ajay Khanna
Sarah Maksimovic
Lauren Mayfield
Renee McCarthy
Darryn Naylin
Opeyemi Obayemi
Norah Osian
Dipen Patel
Vaibhav Patel
Manish Shah
Monica Smith
Simona Williams

MPhA 2018 Mid-Year Meeting

Sunday, February 18, 2018

Thank you to all who attended the MPhA 2018 Mid-Year Meeting!

And a special thank you to Clarion Brands, Pharmacists Mutual, Compliant Pharmacy Alliance, HealthSource Distributors, QS1, the Maryland Board of Pharmacy, Pfizer, and the University of Maryland School of Pharmacy for their support of this meeting!



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Continuing Ed

Falls Prevention in Older Adults

Review of Fall Risk Increasing Drugs (FRIDs) and the Role of the Pharmacist

By Jazmin Turner, PharmD, BCGP, Notre Dame of Maryland University School of Pharmacy

Pharmacist Learning Objectives

After completing this activity, the participants will be able to:

1. Recognize the prevalence and disease burden of falls in older adults in the United States
2. Identify intrinsic, extrinsic, and situational risk factors for falls
3. Identify medications that can cause falls and describe how they cause falls
4. Identify three ways pharmacists can help prevent falls in older adults

Pharmacy Technician Learning Objectives

1. Recognize the prevalence and disease burden of falls in older adults in the United States
2. Identify medications that can cause falls and describe how they cause falls

Keywords

- Falls prevention
- Fall risk increasing drugs (FRIDs)
- Older adults

Introduction

A fall is defined as unintentionally coming to rest on the ground, floor, or other lower surface.[1] It does not need to cause an injury; however, the general public typically associates a fall with that outcome. Due to this misperception, approximately 75–80% of falls without injury go unreported.[2] Every minute of every day, an older adult suffers a fall and one in four adults over the age of 65 falls on an annual basis, according to the Centers for Disease Control and Prevention (CDC).[3] This makes falls the leading cause of injury, both fatal and nonfatal, in older adults.[4] A senior dies from a fall every 19 minutes; however, less than half talk to their doctors about falling.[3,5] In Maryland in 2014, 83% of fatal falls occurred amongst older adults and fall-related hospitalization costs totaled $253 million.[6]

Falls can cause head injuries and arm, ankle, wrist, and hip fractures. Over 95% of hip fractures are caused by falls and the risk of a fracture increases with age. After sustaining a fracture, many older adults are no longer able to live independently and may have to be institutionalized.[7] Head injuries in older adults are especially concerning due to a higher prevalence of comorbidities that predispose them to bleeding and the use of anticoagulants and antiplatelet agents. Warfarin users have a mortality rate six times that of non-warfarin users and antiplatelet users have a three times increase in mortality.[8] Older adults who have fallen often retain a fear of falling, which leads to physical deconditioning, muscle weakness, and social isolation which, in turn, further increases the patient's risk of falling.[2]

The purpose of this article is to review the various pharmacologic and non-pharmacologic causes of falls in older adults and provide strategies for pharmacists to become involved with falls prevention in the community.

Non-Pharmacologic Fall Risk Factors

Falls are typically multi-faceted in nature — they occur due to a combination of intrinsic (patient-specific), extrinsic (environmental), and situational factors.[2] Pharmacists should be knowledgeable about these risk factors so they can make holistic recommendations to their patients.

Intrinsic Risk Factors

While age itself is a risk factor for falling, physiologic changes associated with aging also contribute to a patient's risk of falling. Adults greater than age 85 were four times as likely to suffer from a fall than adults ages 65–74. There are normal gait changes associated with aging: slower walking speed, stiffer movements, impaired balance. There are also pathological gait changes associated with neurological conditions such as Parkinson's disease. Both types of gait changes are associated with a higher risk of falls. Other conditions such as visual impairment, depression, heart rhythm disorders, vitamin D deficiency, vestibular dysfunction, and cognitive impairment are additional intrinsic factors that pharmacists should screen their patients for when doing a fall risk assessment.[2]

Extrinsic Risk Factors

Hazards in the home increase a patient's risk for having a fall. Poor lighting coupled with clutter in

the home and objects such as unsecured throw rugs, can be dangerous for an older patient. Completing modifications, such as installing grab bars, railings, and increasing lighting, can make the home safer.[7] Proper footwear is also important. Wearing slippers, walking barefoot, walking with socks, or wearing high-heeled shoes all increase a patient's fall risk. It is recommended that older adults wear properly fitted shoes with hard, slip-resistant soles and a heel height of less than 2.5 centimeters (less than one inch).[9]

Situational Factors

A common scenario would include something similar to the following: a patient waking up in the middle of the night due to polyuria or nocturia caused by diuretic medications subsequently slipping on a throw rug or tripping over furniture due to poor lighting and clutter.

Fall Risk Increasing Drugs (FRIDs)

Anticholinergic Drugs

Anticholinergic medications are listed on the Beers Criteria for their myriad of adverse effects such as dry mouth, constipation, confusion, ataxia, dizziness, mydriasis, delirium, cognitive impairment, and falls [Table 1].[10,11] Approximately 8–37% of older adults utilize anticholinergic medications, due in part to their over-the-counter availability.[12] Scales such as the Anticholinergic Cognitive Burden Scale (ACB) and Anticholinergic Risk Scale (ARS) rank the anticholinergic activity of medications into groups with scores of one, two, and three; the higher the score, the higher the anticholinergic load and the greater the risk of side effects.[13]

Studies have shown that anticholinergic medications are associated with a decline in lower limb and overall physical function, slowed gait speed and reaction time.

Table 1. Examples of Anticholinergic Medications[10]

Medication Class	Examples
First generation antihistamines	Diphenhydramine, chlorpheniramine, hydroxyzine
Antiparkinson agents	Benztropine, trihexyphenidyl
Antipsychotics	**First Generation:** Chlorpromazine, thioridazine **Second Generation:** Clozapine, olanzapine
Antidepressants	**Tricyclic Antidepressants (TCAs):** Amitriptyline, nortriptyline **Selective Serotonin Reuptake Inhibitors (SSRIs):** paroxetine
Antispasmodics	Dicyclomine, scopolamine
Skeletal muscle relaxants	Cyclobenzaprine, orphenadrine
Urinary incontinence	Oxybutynin, trospium

They also have been associated with cognitive impairment, which is independently associated with falls.[14] In a study by Rudolph and colleagues, it was estimated that an ARS score of three would likely result in at least two anticholinergic adverse effects in more than 70% of their study population.[15]

Cardiac Drugs

There are conflicting reports regarding whether antihypertensives increase the risk of falls and the doses at which they are more likely to cause falls. The proposed mechanism is through hypotension and syncope. Antihypertensive therapy should not be withheld from older adults due to concerns about falls because studies, such as the Hypertension in the Very Elderly trial, have shown that therapy decreases the risk of death from stroke and death from any cause. Patients newly prescribed antihypertensive therapy seem to be at a higher risk of falling when compared to chronic users. This is particularly true for diuretic medications. Thiazide diuretics appear to have the highest risk of causing a fall within the first few weeks of therapy initiation. This may be due to polyuria leading to a reduction in plasma volume and orthostasis.[16,17] Loop diuretics pose the greatest risk within the first week of initiation.[18] Additionally, a study by Lipsitz and colleagues showed that patients taking either an ACE inhibitor (ACE-I) or an angiotensin receptor blocker (ARB) have a lower risk of falls than patients not taking these medications.[1]

Psychoactive Medications

Antipsychotic medications are commonly prescribed in older adults to treat behavioral and psychological symptoms of dementia (BPSD). In addition to the warnings about increased risk of death when used in this manner, a study by Fraser and colleagues found that newly prescribed antipsychotics were correlated with a 52% increased risk of a serious fall and a 50% increased risk of a nonvertebral osteoporotic fracture.[19] Food and Drug Administration (FDA) labeling on many antipsychotics have been updated to include warnings about the increased risk of falls and both first and second generation antipsychotics carry this risk. The proposed mechanisms are: anticholinergic adverse effects, extrapyramidal symptoms, sedation, and hypotension.[20]

Benzodiazepines and sedative-hypnotics increase fall risk by causing confusion, sedation, slowed reflexes, and cognitive impairment. According to the Beers Criteria, short-acting benzodiazepines do not carry a lower risk of falls than long acting ones.[10] According to a study of Medicare patients by Tom and colleagues, use of zolpidem, not eszopiclone, led to an increased risk of hip fracture and traumatic brain injury which necessitated hospitalization. The low utilization of zaleplon in this study made it underpowered to detect the true risks associated with it. Therefore, more studies are needed to determine if there are key differences among sedative hypnotics in increasing fall risk in older adults.[21]

Depression is a risk factor for falls through several potential mechanisms. Cognitive deficits and inattention coupled with psychomotor changes leading to gait instability can all make a patient unsteady on their feet and more likely to trip over hazards. Depression also leads to lower amounts of exercise which causes muscle weakness. A fear of falling due to a history of falls can be disabling to patients and can cause social isolation, which can worsen depression. It can also cause the patient to change their gait, which increases their likelihood of falling. Antidepressants have also been associated with an increased fall risk.[22,23]

Selective serotonin reuptake inhibitors (SSRIs) were initially thought to be safer alternatives to tricyclic antidepressants (TCAs) due to limited anticholinergic affects (except for paroxetine). However, there is mounting evidence that SSRIs can cause falls as well.[24] The risk of falling appears to be the highest within the first several weeks of therapy initiation.[22] Current studies have focused on TCAs and SSRIs, with limited studies on other classes of antidepressants and limited information on specific medications and doses.[23] As a clinician, one must weigh the risks of depression itself with the risks and benefits of antidepressants when looking to treat a patient's psychiatric condition while not exacerbating the risk of falls.

Treating seizures in older patients poses a challenge, as clinicians must balance the risk of falls during seizure episodes with the adverse effects of anticonvulsants, which include ataxia, dizziness, and unsteady gait. The Study on Male Osteoporosis and Aging (SOMA) found that anticonvulsant therapy was associated with a 2-3-fold increased risk of a falling.[25] Anticonvulsant drugs are also associated with an increased fracture risk, with patients who take more than one anticonvulsant and/or an enzyme-inducing anticonvulsant at a higher risk.[26]

Analgesics

Sedation and impaired coordination are the primary mechanisms by which opioids can cause falls. These effects are likely dose-related. A Canadian population-based cohort study found that the mean prescribed opioid dose exceeded the adult dosing recommended by the World Health Organization by 50%.[27] Due to physiologic changes associated with aging, opioid therapy should be initiated in doses that are 25–50% lower than that of younger, healthy adults.[28] This sharp contrast is appropriate compared to actual dosing combined with concurrent psychoactive medications which places older adults at a higher risk of adverse effects. A meta-analysis found that patients who were prescribed opioids had a 38% higher risk of fracture when compared with those who were not prescribed opioid therapy.[29] While all opioids pose risks to older adults, meperidine and pentazocine specifically should be avoided.[10]

When looking at other analgesia options, NSAIDs have also been associated with an increased risk of falls. This medication class has not been studied as intensely as opioids when analyzing fall risk; however, it is important to consider as approximately 20-30% of older adults take NSAIDs on a daily basis. NSAIDs, particularly indomethacin, can cause adverse CNS effects because they cross the blood-brain barrier.[30] For mild to moderate pain, a patient can take acetaminophen, salsalate, ibuprofen, or naproxen if they have an eGFR greater than 30 mL/min and do not have heart failure; these should be given with a proton pump inhibitor to reduce the risk of a gastrointestinal bleed.[31]

Hypoglycemic agents are not always listed as FRIDs, but they are important to scrutinize as there are studies that correlate hypoglycemia with an increased risk of falls. Recognizing hypoglycemia in older adults poses difficulties due to the presence of cognitive impairment and decreased autonomic symptoms, such as tachycardia and sweating, in response to low blood glucose. Hypoglycemia is often underreported to healthcare providers, which can be dangerous if a patient's diabetes regimen needs to be adjusted. It was found that the 4.7% of older adults with type 2 diabetes and a documented hypoglycemic episode within the past year had a 70% increased chance of a fall-related fracture. Patients who were prescribed insulin were found to be at a higher risk of falls than patients prescribed only oral agents. Among oral agents, sulfonylureas had the highest risk of hypoglycemia. While thiazolidinediones, such as pioglitazone, do not increase the risk of hypoglycemia, they do increase the risk of fractures. Therefore, the risks of therapy must be balanced as microvascular complications from uncontrolled diabetes, such as peripheral neuropathy, diabetic

foot ulcers, and retinopathy can also increase falls.[32]

Guidelines & Screening Tools

The **American Geriatrics Society** has specific guidelines for the prevention of falls. It is recommended that patients are asked the following questions at least annually:

1. Have you had 2 or more falls in the past 12 months?
2. Are you presenting with an acute fall?
3. Do you have difficulty with walking or balance?

If the patient has a positive response to any of the screening questions, then that is a trigger for further evaluation and assessment of fall-related risk factors. The guidelines specifically mention medication minimization as a potential intervention to reduce a patient's risks. Psychotropic medications in particular are targeted and it is advised to withdraw those types of medications, if possible, or to reduce the dose if medical conditions necessitate chronic psychotropic therapy. The guidelines also aim at addressing intrinsic and extrinsic risk factors, such as visual impairment, arrhythmias, vitamin D supplementation, and home hazards. They recommend Vitamin D 800 IU in all older adults at risk of falls.[24]

The **CDC Stopping Elderly Accidents, Deaths, and Injuries (STEADI)** initiative has materials for both healthcare providers and patients and it has three main components: screen, assess, and intervene. The Stay Independent brochure can be completed by a patient; a score ≥ 4 should trigger a multi-factorial assessment. Patients are separated into three categories: low risk (a score less than 4), moderate risk, and high risk and each category has different interventions.[33] **The American Society of Consultant Pharmacists** and the **National Council on Aging** have paired together to create a Falls Risk Reduction Toolkit, which is a companion to CDC STEADI. This toolkit provides a more in-depth medication evaluation in order to identify medication-related problems that may be contributing to falls.[34]

Beasley and colleagues created a **Medication Fall Risk Score** tool that separates classes of medications into high risk (3 points), moderate risk (2 points), and low risk (1 point)

PATIENT CASE

Mrs. Roland is a 67-year-old patient who presents to your medication management clinic after being referred by her primary care provider for a medication review. She had a fall last month and was treated at the emergency department for a right arm fracture. Mrs. Roland has a past medical history which includes: type 2 diabetes, generalized anxiety disorder, hypertension, mild Alzheimer's disease, and dyslipidemia. All labs are within normal limits. She is currently prescribed: metformin 1000 mg PO BID, clonazepam 1 mg PO TID, lisinopril 5 mg PO daily, and atorvastatin 40 mg PO daily. She describes feeling tired and lightheaded right before she stumbled, slipped on a throw rug, and fell in the kitchen in the middle of the night. In the emergency room, she was prescribed oxycodone/acetaminophen 10/325 mg 1 tablet PO Q6H PRN.

1. What intrinsic risk factor does Mrs. Roland have that increases her risk of a fall?
   a. Dyslipidemia
   b. Throw rug
   c. Mild Alzheimer's disease
   d. Poor lighting in the kitchen
2. What is an issue you have identified with this medication in terms of her fall risk?
   a. Dosing frequency
   b. Risk of constipation
   c. Risk of nausea
   d. High dose
3. What would you recommend for the primary care provider to prescribe to treat her anxiety?
   a. Duloxetine 30 mg PO daily
   b. Duloxetine 90 mg PO daily
   c. Fluoxetine 20 mg PO daily
   d. Sertraline 25 mg PO daily
4. Mrs. Roland would also like to know if there is anything that she can take over the counter to reduce her risk of falling. You reference the AGS guidelines and recommend:
   a. Vitamin D 400 IU
   b. Vitamin D 800 IU
   c. Vitamin D 1000 IU
   d. Vitamin D 2000 IU

Answers on page 18

Table 2. Therapeutic Alternatives for Several Classes of FRIDs[10]

Medication Class	Alternatives
First generation antihistamines	• Intranasal normal saline • Second-generation antihistamine • Intranasal steroids
Anticholinergic antiparkinson agents	• Carbidopa/levodopa
Anticonvulsants	• New-onset epilepsy o Lamotrigine, levetiracetam (newer drugs) preferred o Calcium/vitamin D supplementation o Bisphosphonate • Neuropathic pain o Serotonin norepinephrine reuptake inhibitors (SNRIs) o Gabapentin o Pregabalin o Topical capsaicin o Lidocaine patch
Benzodiazepines Non benzodiazepine hypnotics	• Anxiety: o Buspirone o SNRI • Sleep — non-pharmacologic options such as: o Behavioral therapy o Sleep hygiene
Long acting sulfonylureas	• Short-acting sulfonylureas (glipizide)
Tricyclic antidepressants SSRIs	• Depression: o SNRI o Bupropion • Neuropathic pain o SNRI o Gabapentin o Pregabalin o Topical capsaicin o Lidocaine patch

medications. Scores ≥ 6 indicate that the patient is at a higher risk of falls and this should trigger a more in-depth medication review.[35] In addition to completing these risk assessments, the pharmacist can also measure patients' blood pressure and alert their providers if they observe orthostatic hypotension as a method of screening for falls.

Role of the Pharmacist

Pharmacists are trained to be aware of drug-drug, drug-food, and drug-disease interactions, understand issues such as anticholinergic burden and potentially inappropriate medications, and apply the concepts of aged-related physiologic changes. This makes them uniquely positioned to help prevent falls as members of the interdisciplinary team. Understanding how an older adult's comorbidities and medications interact with the physical, psychological, and pharmacokinetic/pharmacodynamic changes of aging is essential. The CDC created a pharmacist-specific falls prevention training in March 2017 and the National Council on Aging (NCOA) specifically mentions pharmacists as having a role in reducing falls in their 2015 Falls Free Strategic Plan[36,37] As pharmacists are being nationally recognized as members of the healthcare team that can help prevent falls, it is essential to get involved. By conducting medication therapy management and comprehensive medication reviews, pharmacists can uncover medication-related problems that increase the risk of falls and address these issues with the prescriber [Table 2].

In a study by Casteel and colleagues, patients of 32 community pharmacists in North Carolina were recruited for medication reviews based on age and number of medications, more specifically psychoactive medications. Pharmacists reviewed the regimens of 73 patients and made [41] recommendations for medication changes. While overall provider acceptance was low (24.4%), this study demonstrates how many interventions pharmacists can make to reduce falls.[38] In a 2011 paper by Flores and colleagues, the pharmacists' role in an interdisciplinary falls clinic was described: obtaining an accurate and detailed medication history, evaluating regimen difficulties, counseling on adherence and proper medication administration, and evaluating high risk medications and drug interactions.[39] In a retrospective observational study that took place in a rehabilitation center, the number of falls among older adults was measured before and after pharmacy intervention. The post-intervention group had a 47% reduction in falls.[40]

Deprescribing is defined as the supervised withdrawal of potentially inappropriate medications to minimize polypharmacy and improve health outcomes.[41,42] In a non-randomized controlled study, cognitive improvement, fall reduction of up to 66% and fracture reduction of up to 10% were seen in patients whose benzodiazepines and other psychotropic medications were reduced or discontinued. Deprescribing has also been shown to reduce costs, improve adherence, and produce positive health outcomes in older adults.[42] A prospective cohort study showed that deprescribing FRIDs was associated with a reduction in falls.43 Pharmacists can have major involvement with deprescribing by identifying potentially inappropriate medications, recommending safer alternatives, counseling, and monitoring patients as medications are reduced and eventually discontinued.

Conclusion

Older adults are at a risk of falling due to a complex interrelationship between physiologic effects of aging, changes in pharmacokinetics and pharmacodynamics, comorbidities, and polypharmacy. Clinicians must balance properly treating a medical condition while minimizing the risk of falls from various medications. Pharmacists are in a unique position to identify FRIDs, consult with prescribers on medication changes, monitor deprescribing efforts, and counsel patients on falls prevention strategies.

ANSWERS

1. **Answer: C** Answers B and D are both extrinsic risk factors. Patients with Alzheimer's disease have been shown to alter their gait pattern and have decreased gait stability. Dyslipidemia has not been shown to be associated with falls. Mrs. Roland expresses concerns about her new oxycodone/acetaminophen prescription because she's afraid about becoming addicted. She's never taken an opioid before and when she took the first dose she felt very sedated. She requests for you to go over the risks and side effects with her.
2. **Answer: D** The dosing frequency of the oxycodone/acetaminophen is appropriate. Constipation and nausea have not been correlated with falls. The dose is too high for an initial dose for an opioid naïve, geriatric patient and increases the risk of adverse effects that could lead to another fall. After talking about the risks of benzodiazepines in older adults, Mrs. Roland is hesitant to discontinue because she's been taking the medication for 10 years. She doesn't believe anything else would be effective for treating her anxiety, although she is afraid of having another fall. You ask for her primary care provider come in and discuss the risk of benzodiazepines with the patient as well and she eventually agrees to a slow taper over the course of several months.
3. **Answer: A** Fluoxetine and sertraline are both SSRIs and they have been shown to increase fall risk. This does not mean that SSRIs are always inappropriate, but they are not first-line for patients at risk of falls. Duloxetine is an SNRI, which is listed as a potential alternative, but 90 mg is too high for a starting dose. An initial 30 mg dose would be the most appropriate.
3. **Answer: B** The AGS Falls Prevention Guidelines recommend Vitamin D 800 IU to prevent falls in older adults.

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Second Quarter 2018: Pharmacy Time Capsule

By: Dennis B. Worthen, PhD, Cincinnati, OH

1993

- NABP Task Force on Pharmacy Technicians issued final report. One recommendation was to standardize the term pharmacy technician as a uniform title designating personnel that assist the pharmacist in the practice of pharmacy.

1968

- Successful human parenteral hyperalimentation first described.

1943

- Microbiologist Selman A. Waksman discovers the antibiotic streptomycin, later used in the treatment of tuberculosis and other diseases

1918

- Prior to 1918, pharmacy services in PHS hospitals were provided through contract services or by Federal civilian employees. In 1918, a reserve corps composed of pharmacists, dentists and engineers were commissioned to serve with physicians in the PHS.

1893

- Virginia University College of Medicine Department of Pharmacy formed (became part of the Medical College of Virginia in 1913).

One of a series contributed by the American Institute of the History of Pharmacy, a unique non-profit society dedicated to assuring that the contributions of your profession endure as a part of America's history. Membership offers the satisfaction of helping continue this work on behalf of pharmacy, and brings five or more historical publications to your door each year. To learn more, check out: ***www.aihp.org***

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State Legislative Update

The 2018 Maryland legislative Session was once again an active session with a host of pharmacy-related bills.

A more comprehensive bill chart can be accessed here: https://bit.ly/2Htbzyp

HB 736/ SB 576
Pharmacy Benefits Managers — Pharmacies and Pharmacists — Information on and Sales of Prescription Drugs

PASSED

Eliminates the "pharmacists gag rule." Prohibits a pharmacy benefits manager from prohibiting a pharmacy or pharmacist from discussing with or providing a beneficiary with information on the retail price of a prescription drug or the amount of the cost share for a prescription for which the beneficiary is responsible.

HB 1349/SB 1079
Pharmacy Benefits Managers — Revisions

PASSED

The bill provides the Commissioner of the Maryland Insurance Administration (MIA) broader authority to request information from PBMs. PBMs may not reimburse a pharmacy or pharmacist less than it reimburses itself or an affiliate for the same product or service, with some restrictions. Clarifies the definition of the MAC List and determines that the MAC fee does not include dispensing fees. MAC list must be accessible in an electronic format with immediate updates used to calculate payments to pharmacies. PBMs are required to have designated personnel to address questions related to appeals within three business days. Upheld appeals will be adjusted to appealing pharmacies with no reverse and rebill, with corrections made to similarly contracted pharmacies on second remittances; and notices sent to others in the network. Appeal denials must include the NDC and the name of the wholesaler where the product was available on the date the claim was adjudicated at or below the MAC price. Bill clarifies MIAs regulatory and enforcement authority and is effective June 2018.

HB 1558
Pharmacists — Dispensing of Prescription Drugs — Single Dispensing of Dosage Units

PASSED

Authorizes a pharmacist to dispense in a single dispensing a 30-day prescription with two refills (90-day fill) without physician authorization.

HB 407/SB 232
Public Health — General Hospice Care Programs — Collection and Disposal of Unused Prescription Medication

PASSED

Requires general hospice care programs to establish a program for medication collection and disposal.

HB 1452 /SB 1223
Controlled Dangerous Substances Registration — Authorized Providers — Continuing Medical Education

PASSED

Amended bill requires prescribers and dispensers to complete two CE on opioid prescribing or dispensing prior to initial CDS registration or the first renewal on or after October 1, 2018. MPhA opposed underlying bill and provided input on amended language. This is a one-time occurrence and is intended to stop the annual submission of legislation requiring health providers to take opioid training.

HB 2/SB 1
Medical Cannabis Commission Reform Act

PASSED

The bill as introduced included several reforms related to diversity and number of permits for cannabis growers and dispensers. MPhA successfully amended the House bill to maintain a pharmacist seat on the Cannabis Commission.

HB 115/SB 13
Electronic Prescription Records Cost Saving Act of 2018

PASSED

Initial bill required all dispensers of a prescription drug to submit dispensing information to CRISP. The House bill was successfully amended to require the Maryland Health Care Commission, in consultation with interested stakeholders, to assess the benefits and feasibility of developing an electronic system to allow health care providers to access a patient's prescription medication history, requires the Commission to report its findings to the Governor and the General Assembly on or before January 2020.

HB 591/SB 549
Health Occupations — Physician Assistants — Dispensing of Drugs Under a Delegation Agreement

PASSED

Allows physician assistants (PA) to dispense medications under a delegation agreement with a physician who has a dispensing permit. MPhA felt the expansion of scope was too broad, with unanswered concerns regarding PA dispensing of opioids and their requirements related to updating the PDMP. MPhA was the only group in opposition to this expansion of scope.

HB 601/SB 1255 — Public Health — Opioids — Dispensing Requirement

FAILED

The bill as introduced required dispensing of an opioid antagonist product with all opioid prescriptions. However, the mandate was only for pharmacists and not all dispensers. We fought against it and its various iterations as it was an unfunded mandate on pharmacies and patients and violated MPhA's policy against mandatory patient counseling in legislation and regulations.

HB 1194/SB1023 — Health – Drug Cost Review Commission

FAILED

This bill was Phase II of the medication affordability initiative spearheaded during the 2017 legislative session. As introduced the Commission would have reviewed prescription drug costs and reported back recommendations to the state. The bill was amended significantly and watered down the intent. As we go to print, a federal appeals court declared last year's price gouging law unconstitutional.

Federal Legislative Update

MPhA participated in the NCPA Congressional Advocacy Summit, April 11-12 in Washington, DC. We visited with the Maryland Congressional delegation with pharmacists and student pharmacists to encourage support for federal provider status for pharmacists and the prohibition of DIR fees in Medicare Part D.

HR 592/S 109
Pharmacy and Medically Underserved Areas Enhancement Act

Recognizes pharmacists as providers under the Medicare Part B program. If passed, pharmacists would be able to perform and be paid for services for patients consistent with their state's scope of practice if their pharmacy is located in a medically underserved area, health professional shortage area, or medically underserved population. Nineteen out of 24 counties in Maryland are considered to be medically underserved. The majority of the MD Congressional Delegation are cosponsors of this bill, except for Reps. Steny Hoyer (D-5) and Andy Harris (R-1).

HR 1038/S 413
Improving Transparency and Accuracy in Medicare Part D Spending Act

Prohibits retroactively reducing payment on clean claims submitted by pharmacies under Medicare Part D. Reps. Joh Sarbanes (D-3) and Jamie Raskin (D-8) are cosponsors.

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Editorial

Reflections, Rhythms and Rewards of Haiti Medical Missions: Five Times and Four Years Later

By Hoai-An Truong, PharmD, MPH, FAPhA, FNAP and Yen H. Dang, PharmD, CTTS-M

"My children, I give you a mission... to relieve suffering" are the lyrics of a song that our driver, and also the pastor and leader of the Carcasse community in the remote southwestern region of Haiti, led us in singing as we drove into the sunset with mountain and ocean on either side of rugged roads on the journey back to Jeremie, one-third of the way back to Haiti's capital Port-au-Prince, after a weeklong medical mission. The 4-hour bumpy ride through rough terrain made several stops on pitch black roads as Pere [Father] Verdieu examined the tire for a potential flat. We found hope and comfort as we gazed into the sky with shining stars to say a quick prayer. Another SUV was close behind with the other half of our team members, including healthcare professionals and interpreters both from the U.S. and Haiti who worked together to care for Haitians during our medical mission, and perhaps relieve some human suffering.

Despite the many hardships that Haiti has faced, there is hope and a vision for the future that exists among many of the Haitian people I met. I came away from the experience with new friends, new perspective, and a new hope for the future of collaborative global health.

– Scott Baker, Pharmacy Student (Haiti Medical Mission 2018)

Our team consisted of our fearless leader Mrs. Pat Labuda, who has traveled to Haiti for over 30 years and speaks Haitian Creole, supported by Dr. Frank Nice, founder of this Haiti medical mission, two physicians, two nurse practitioners, two nurses, two University of Maryland Eastern Shore (UMES) faculty pharmacists, three UMES student pharmacists, and four interpreters. Together we conducted a 5-day primary care clinic, seeing 1,011 patients, treating 1,307 medical conditions, and dispensing 1,877 prescriptions. With limited medications and supplies, we managed to last through five full days, working from 8 a.m. to 7 p.m. We had the opportunity to serve patients ranging from 9 days old to 96 years old by providing general physical assessments, lab tests, medication dispensing, and hosting a focused women's health education session. It was a humbling experience knowing some patients had to walk many miles, and in some cases over mountains from another town, to wait in long lines in the heat on dirt ground for hours to receive the only medical care for the year, or years, and then return home with medications and a sense of comfort.

We found our sense of comfort in knowing that while we had left our daily lives with our family and paying jobs for this volunteer opportunity, the gratitude of our

Jessica Wearden with children.

Maheder Dachew.

Visiting the hospital pharmacy.

It was astonishing to see how many people needed medical attention but were not able to receive it due to distance and money. There were days we worked past clinic hours to attend to as many patients as we could knowing that we were their only source of medical attention for a while. It was humbling to see many of their diseases are so prominent solely due to lack of nutrition, hygiene, and education, all of which we take for granted here in the United States.

– Thomas Tran, Pharmacy Student (Haiti Medical Mission 2018)

fellow Haitian brothers and sisters was beyond our comprehension. The words of appreciation from the priest and interpreters, as we gathered to reflect and relax on our last night under the star-filled Carcasse sky surrounded by the rhythms of musical and dance performances, touched our hearts. It was peaceful and comforting as we held hands with our Haitian friends and danced to the music — the universal language of humanity. As our minds wandered into the cadence of the night, with the sounds of crickets, insects, cow, and even early-rising roosters, our thoughts traveled back to 4 years ago during the inaugural UMES medical mission to Haiti in May 2014.[1,2]

Orphanage mission team and children.

No one tells you how much you will fall in love with the country and the children you meet and how a piece of you will always stay with them.

– Jessica Wearden, Pharmacy Student (Haiti Medical Mission 2016)

Time flies as we capture memories of global health services. UMES has partnered with St. Francis of Assisi Catholic Church and received fundraising support from non-profit organizations, including Health and Education for Haiti and International Community Initiatives, for five medical missions to Haiti from 2014 to 2018 providing 'beyond the classroom' global health experiences for more than 30 pharmacy, physical therapy, and physician assistant students in the real-world.[1,2] The impact on our students to provide compassionate, cultural, and competent health care for diverse patient populations in a developing country is immeasurable.

This trip was a perfect mixture of overcoming challenges and serving a patient population that is in need.

– Truptiben Sindhi, Pharmacy Student (Haiti Medical Mission 2018)

In addition to applying their academic knowledge and skills, students enhanced their abilities in communication, cultural competence, health literacy, leadership, and providing compassionate care. Besides appreciating the necessities of life - food, water, and shelter — we were challenged to work with limited resources and live in the community of our patients. Such challenges included antibiotic substitutions, pre-natal vitamins usage for all who needed multivitamins, and cutting up bottles as inhaler spacers

We were able to swim in the river near the orphanage and enjoy some simple pleasures like skipping stones, right next to some of the local children. It was a settling experience, contrasted by the devastation we have seen in patients and in the country's infrastructure.

– Marc McDonald, Physical Therapy Student (Haiti Medical Mission 2016)

We managed to control our emotions while facing extreme poverty, worked creatively with what we had, and slept when we could at the end of the long days. We walked along the trails with children, dipped our feet into the ocean, and hiked through the Haitian mountains — all in an attempt to relax and recharge after tough days. We left Haiti with a sense of fulfillment and gratefulness for what we have in life. While our mission to relieve suffering is not complete, our fifth UMES medical mission was a rewarding experience, with many of us promising to return to Haiti again.

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Executive Director's Message

Some days it seems a little hard to tell, but Spring is easing its way in. With it brings MPhA's participation in annual national pharmacy events, longer days, fresh perspectives and new opportunities.

The APhA Annual Convention is always a wonderful time to gather with our Maryland Phamily! With sponsorship from our three schools of pharmacy, we welcomed nearly 150 attendees at our annual "must attend" Maryland Pharmacy Night. In Nashville, we were able to reconnect and celebrate the achievements of Maryland colleagues and students. I also recently participated in NCPA's Congressional Advocacy Summit with several pharmacy owners and students. We educated congressional leaders about on-the-ground pharmacy issues and advocated for bills that impact pharmacy practice and provider status. I also advocate for my own profession and participated in the American Society of Association Executive's Association Advocacy Day with other leaders of professional societies and non-profits. Our goal was to educate members of Congress about the power of associations, and how potential modifications to tax legislation could impact the work we do.

Spring brings a new round of graduations. It is an exciting time. The Class of 2018 will soon join the profession. They have been trained on the latest and greatest in pharmacy practice, leadership, and professionalism. They have experienced various practice settings and cultivated long-lasting relationships with their peers, professors and employers. I was pleased to have renewed MPhA's commitment to professional development by serving as a rotation site. We had wonderful students who contributed to our work and learned how important MPhA's role is in advocating for the profession. MPhA continues to push to ensure that the scope of practice in Maryland is up-to-date so seasoned professionals and new graduates can practice at the height of their degrees. As I think about the upcoming graduations, I am reminded of a quote by Arthur Ashe: "Start where you are; use what you have; do what you can." And so to our newest new practitioners, I say: Start at your workplace, residency or fellowship, be empowered that you are working in a profession that is one of the most trusted in the healthcare industry. Utilize your skills and your network (you earned it!). Do what you can to stay up-to-date and connected to your colleagues by maintaining your membership and/or investing your time and talent in an MPhA activity or committee. The connections and opportunities you gain will benefit you far beyond your contributions.

Spring also means the end of another legislative session. The 2018 session was full-throttle. We successfully advocated for bills that will provide greater transparency, regulation and enforcement of PBMs and limited opportunities for drug diversion. We watered down bills that would have added extensive additional CE requirements and killed bills that would have forced unfunded mandates on pharmacists and patients. Legislative session is a bargaining game. Spring gives us an opportunity to reflect on the session, think about new opportunities and refresh strategies for the next go-around. As we get closer to the summer recess, I encourage you to invite your General Assembly and Congressional representatives to your practice site. These connections build their familiarity with you and pharmacy-related topics.

What's new? We have introduced a new Advocacy Focus Group Webinar series to help you learn about and give feedback on issues that impact different practice settings. We are also bringing back the New Practitioner Happy Hour, with connection points in different parts of the state. We hope our new practitioners will take advantage of these networking opportunities.

Spring gives us an opportunity to reflect on the session, think about new opportunities and refresh strategies for the next go-around.

As always, I look forward to the 136th Annual Convention, where we will bring our families together to soak up some sun, learn, and celebrate professional contributions to MPhA and Maryland pharmacy. We will be back in Ocean City! We are working hard to enhance the Annual Convention with new programming, while maintaining our favorite MPhA traditions.

Looking forward to seeing you soon!

Aliyah N. Horton, CAE
Executive Director

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Convention Wrap-Up

Review of another great program of CE, networking and fun!

Award Winners

Congratulations to the 2018 MPhA Excellence in Pharmacy Awards recipients!

MPhA News

Congrats to the new PharmD Graduates and 2018 MPhA Outstanding Student Pharmacist Achievement Award winners!

Continuing Education

Chronic Obstructive Pulmonary Disease Treatment Update: Review of Recent Guideline Changes and Recommendations

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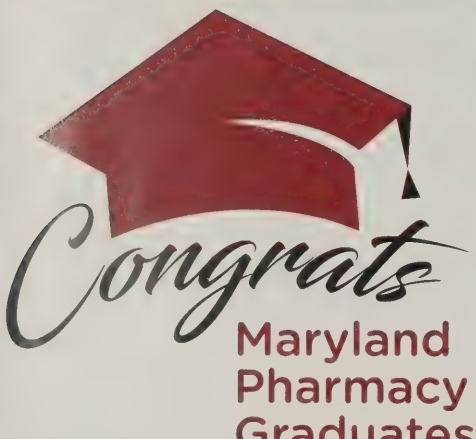

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Frank Nice, RPh, DPA, CPHP

STAFF
Aliyah N. Horton, CAE, Executive Director
Lauren Williams, Director of Programs and Membership Engagement
Shawn Collins, Membership Services Coordinator

CONTRIBUTORS
NASPA Services Company, LLC, Editorial
Katy Pincus, PharmD, BCPS
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Maryland Pharmacists Association, 9115 Guilford Road, Suite 200, Columbia, MD 21046, call 443.583.8000, or email aliyah.horton@mdpha.com.

President's Pad

I look forward to engaging each of you to bring your ideas forward and transform our association through innovation. Let us become imagineers and see what we can build together.

Dear MPhA Members,

Thank you for giving me the opportunity to serve as your association president. I am very appreciative of the support and guidance that our member volunteers continue to provide. As I prepare to share my vision for MPhA with you, I am inspired by your energy and excitement, and I look forward to serving you as we work to achieve our strategic plan priorities and increase membership value.

As I put pen to paper to draft these remarks, I reflected upon my own MPhA journey which started as a first-year student pharmacist. I remember my first visit to the Kelly Building, where pharmacists talked as friends and worked to improve the future of the profession amidst a 1950s pharmacy exhibit. These trailblazers were passionate about their involvement, and it was their vision that led to exciting developments like the MTM summit and our permanent home at 9115 Guilford Road.

This home, like our meetings and events, is the product of creative ideas driven by passion and hard work. MPhA has a rich history of major accomplishments because members like you are given a voice. Through an environment that stimulates and facilitates member participation, everyone can make a meaningful impact by contributing their ideas and interests. With your support, we can shape the association through this year's theme of "Imagineering: Transforming MPhA through Innovation."

Imagineering, which combines imagination with engineering, is the process of implementing creative ideas in a practical way. It is this concept that will serve our association well as we build the infrastructure for a stimulating environment that supports member participation. It starts by laying the foundation for the MPhA of tomorrow by reflecting upon our past and engaging the present.

I envision a vibrant member community actively increasing the value proposition for joining our association, creating a place where pharmacists, technicians, student pharmacists, and friends can have fun by volunteering their time, sharing ideas, and participating in events. To jumpstart this effort, I have refreshed our committees with new leadership to pull in that energy from all aspects of our membership and take advantage of unique experiences. These committees will not only plan events, but also encourage member contributions. In addition, you will notice a concerted effort to engage our Past Presidents on each committee, tapping into their knowledge and experience. We also are supporting first-time trustees through a mentorship program to ensure we have a strong pipeline of future leaders.

With this foundation, MPhA will have greater capacity to shift ideas into production, thereby generating membership value through rapid yet sustainable growth. The association will examine value in the non-traditional sense in order to provide educational entertainment, a multitude of convenient touchpoints connecting you

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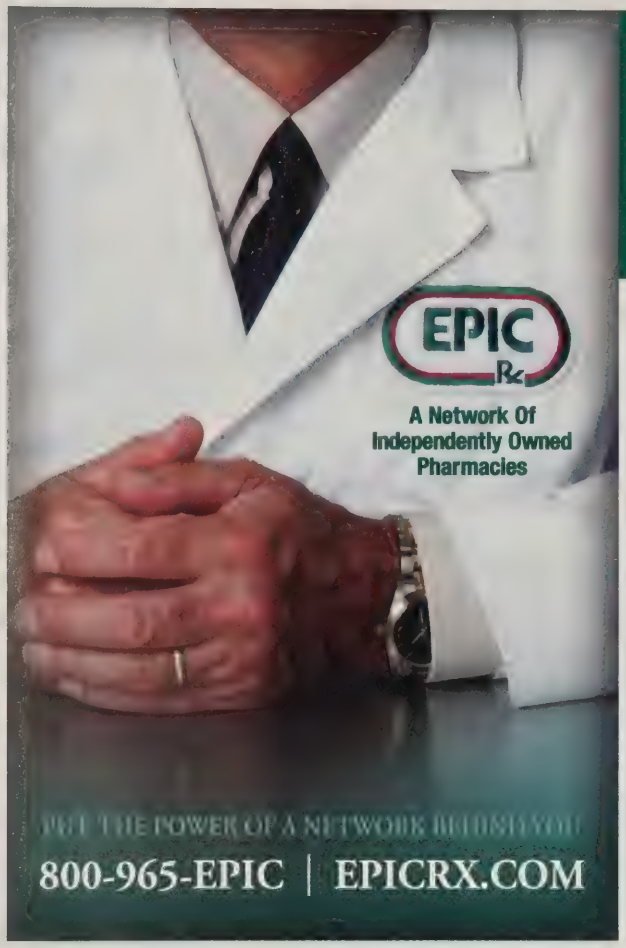

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President's Pad *continued*

with the organization, and ensuring you are personally and professionally satisfied with the membership experience.

We will work to ensure MPhA is responsive to your interests and promotes events in different venues across the state and through mobile and web-based technology. By working together, Let us work together and create the meaningful experiences that make fun MPhA memories. Transforming MPhA through innovation is not limited to events — this is also an opportunity to consider new approaches to achieve our strategic goals. We will be looking to enhance our membership offerings to make it easier to become a member. By placing a focus on family and community engagement, we can bring additional value to your membership. And through organizational development, we will plan major association events like our conventions with additional lead time to maximize attendance.

You are essential to the success of this association. Your ideas will drive the MPhA of tomorrow. If you have not yet had the opportunity to volunteer on a committee and would be interested in doing so, let us help you become connected so you can help make a difference.

With that, I want to thank everyone again for their support this upcoming year. I look forward to engaging each of you to bring your ideas forward and transform our association through innovation. Let us become imagineers and see what we can build together.

Thank you,

Chai Wang

Chai Wang, PharmD, BCPS, AE-C
President, Maryland Pharmacists Association 2018–2019

Member Mentions & News You Can Use

MPhA Members Honored with AACP Award

Dr. Nicole Culhane, Assistant Dean, Experiential Education, Notre Dame of Maryland University School of Pharmacy, received the Excellence in Experiential Education Award from the American Association of Colleges of Pharmacy Experiential Education Section at the annual meeting in July 2018.

Toney Appointed to BOP

Congratulations to Rhonda M. Toney, who was recently elected as Secretary of the Maryland Board of Pharmacy. Toney was appointed as an at-large representative on the Board, and is serving her first term through 2021.

With Sympathy

Delegate Ted Sophocleus passed away on June 8. Sophocleus was one of the longest serving public officials in Anne Arundel County history and the only pharmacist serving in the Maryland General Assembly. Our condolences to the family, friends and colleagues of Del. Sophocleus. A funeral service was held on Friday, June 15. Donations may be made to Opportunity Builders, Inc. of Millersville in Sophocleus' memory.

Reminder: PDMP Mandated Use as of July 1

Effective July 1, 2018, Maryland law requires controlled substance prescribers and pharmacists to request and assess data from the prescription drug monitoring program (PDMP) in certain prescribing and dispensing situations. The below materials detail when you are required to check the PDMP and where exceptions exist — both clinical and technological — and how to appropriately document your actions.

The Maryland Department of Health (MDH) anticipates no issues related to PDMP access. However, if you encounter any challenges, you should use reasonable clinical judgment in deciding whether to prescribe or dispense an opioid or benzodiazepine. An inability to view PDMP data does not legally prevent you from prescribing or dispensing.

The Proceedings of the Maryland State Pharmaceutical Association Digitization Project is Complete!

With support from the MPhA Foundation, the History Committee has been working on several projects to highlight the contributions of MPhA to Maryland pharmacy history. One effort of the project was to digitalize documents held at the University of Maryland. MPhA proceedings from 1985–1955 are now available in the University of Maryland Baltimore's Digital Archive.

MPhA Helps Launch RALI MD

MPhA has joined as a founding partner of the Rx Abuse Leadership Initiative (RALI) of Maryland. It is an alliance of more than a dozen local, state, and national organizations committed to finding solutions to end the opioid crisis in Maryland. RALI focuses on raising awareness about appropriate drug disposal.

Aliyah N. Horton, Neil McGarvey and MPhA President Cherokee Layson-Wolf

The program was launched at MPhA member Neil McGarvey's pharmacy, Annapolis Professional Pharmacy, with Maryland House Speaker, Delegate Mike Busch. Education events have also been held at community meetings with members of the Maryland General Assembly. RALI is developing future events in Western Maryland and on the Eastern Shore.

Changes to General Assembly Committee Leadership

Delegate Joseline Peña-Melnyk will become the Vice Chairman of the House Health and Government Operations (HGO) Committee. Delegate Pena-Melnyk has served in the House and on the Health & Government Operations Committee since 2007, and as the Public Health & Minority Health Disparities Subcommittee Chair since 2015.

Delegate Peña-Melnyk has been a strong advocate for the pharmacy profession. She has supported efforts related to enhancing collaborative practice authority, pharmacy technician registration waivers for pharmacy students, and contraceptive prescriptive authority, among others. She will replace Delegate Eric Bromwell who will become the Vice Chairman of the House Economic Matters Committee.

Both House and Senate Committees that oversee healthcare issues are seeing significant turnover. On the House side, at least seven members of HGO Committee lost their primaries or chose not to run for reelection. In the Senate, the Senate Finance Committee chair, Senator Mac Middleton, lost his primary, and the vice chair, Senator John Astle, chose not to run. And the Education, Health, and Environmental Affairs Committee chair, Senator Joan Carter Conway, also lost her primary.

MPhA will engage in outreach and education to get the new members of these important committees up-to-speed on pharmacy practice issues.

2017 Price Gouging Law

The U.S. 4th Circuit Court of Appeals issued a ruling denying the Attorney General's request for a rehearing to uphold Maryland's 2017 prescription drug anti-price-gouging law. It is unclear at the time of publication, whether State Attorney General Brian Frosh will seek a Supreme Court appeal. In the meantime, Members of the General Assembly are holding town hall meetings across the state to discuss prescription affordability. These town halls will inform how the Delegates proceed on the issue during the 2019 Session.

We Work for Health Maryland Summit

As a co-chair/partner of We Work for Health (WWFH) Maryland, MPhA works with a diverse mix of Maryland organizations to promote the social and economic value of the biopharmaceutical and life sciences sectors in Maryland. Our partners include biotechnology and pharmaceutical companies, as well as state and local chambers of commerce, academic and research institutions, labor and patient advocate groups, physicians, and healthcare providers. Annually, MPhA participates in a WWFH summit with other state partners in Washington, DC. The summit included meetings with the Maryland congressional delegation. The collective Maryland team had meetings with the offices of the entire 10-member delegation and MPhA staff participated in eight.

WeWorkforHealthMD representatives with Senator Chris Van Hollen

Maryland Technician Consensus Conference

MPhA staff and members participated in the development and implementation of the Maryland Pharmacy Technician Consensus Conference. The conference was held on June 21. MPhA served as a sponsor of the event, along with the Maryland Board of Pharmacy, Maryland Association of Chain Drug Stores, Maryland Pharmacy Coalition, MPhA, Maryland Society of Health-System Pharmacy, Notre Dame of Maryland University School of Pharmacy, University of Maryland School of Pharmacy, and University of Maryland Eastern Shore School of Pharmacy.

Attendees included a broad swath of professionals and stakeholders engaged in the education, hiring, and supervision of pharmacy technicians. The consensus conference aimed to identify the optimal knowledge, skills, and abilities pharmacy technicians need; educational requirements; and potential regulations related to how technicians practice. MPhA members and leadership were well represented and provided key perspectives from various practice settings.

The consensus conference report is under development and will be made available to the membership upon its release.

Continued on next page

Phi Lambda Sigma and the Maryland Pharmacists Association Reunite

Saniya Chaudhry, President, NDMU Phi Lambda Sigma Delta Beta Chapter
James Bresette, PharmD, UMES School of Pharmacy, Phi Lambda Sigma Delta Nu Chapter Co-Advisor

On Saturday June 2, 2018, Phi Lambda Sigma welcomed 41 pharmacists and pharmacy students to the Notre Dame of Maryland University School of Pharmacy. Phi Lambda Sigma partnered with MPhA and the MPhA Foundation to bring graduates another opportunity to excel at the Multi-State Pharmacy Jurisprudence Exam (MPJE). The 7-hour review session was planned and implemented by the three school Phi Lambda Sigma chapters with Dr Andrew York, PharmD, J.D., Phi Lambda Sigma alumnus and MPhA member instructing.

This partnership marks the second consecutive year that students, recent graduates and pharmacists entering Maryland pharmacy practice were presented content on pharmacy law, efficient studying techniques and how to excel when taking the MPJE. The three chapters planned this powerful one-day session through 3 months of weekly teleconferences. The planning committee is also working to improve the available options by offering a recording of the live session and supplemental podcasts to augment the live session. These content options will be available for all MPhA members through the website.

This year's MPJE workshop brought in 33 new MPhA members and the overall satisfaction with the MPJE session was rated as highly or very highly satisfied, receiving 4s and 5s on all aspects of the course.

Phi Lambda Sigma and the MPhA Foundation aim to continue this partnership, offering the MPJE preparation course again in 2019. Phi Lambda Sigma, the MPhA Foundation and MPhA will continue to work together to successfully prepare all pharmacists seeking Maryland licensure to pass the MPJE and demonstrate the value and benefit of MPhA membership. ●

Member Mentions & News You Can Use *continued*

Pharmacy Gag Rule Press Conference

MPhA Trustee Richard Debenedetto participated in a press conference with Representative John Sarbanes to thank State Senator Kathy Klausmeier and Delegate Eric Bromwell for their sponsorship of the legislation that bans the "pharmacist gag rule." ●

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History: How and When MPhA Was Formed

Murhl Flowers, RPh, Co-Chairman, MPhA History Committee

MPhA History Committee

In April 2016, MPhA formed a History Committee to research and produce a written history of MPhA. The committee's goal is to preserve MPhA history with written documentation chronicling the history of the Maryland Pharmacists Association. This has proven to be quite a challenge. The original name of the association, established in 1883, was the Maryland Pharmaceutical Association. Our journal was not established until 1925; consequently, we only have information from 1925 to the present. It is extremely difficult to find the activities and proceedings from 1883 to 1925.

The committee is primarily composed of past MPhA presidents but participation is open to any interested member. So, if you are interested in joining, please let the office know.

Association Establishment

The Maryland College of Pharmacy was organized in 1841, making it the fourth school of pharmacy in the United States. Many of the school's graduates and other Maryland pharmacists were instrumental in the founding of the American Pharmaceutical Association (APhA) in 1852. Annual meetings of APhA were held in Baltimore in 1856, 1863, 1870, and 1898.

One of APhA's outstanding efforts was to encourage the formation of state and local pharmaceutical associations. Efforts were made by the Maryland College of Pharmacy in 1868 to form a state association in Maryland. However, there was not enough support from the ranks to sustain an association at that time.

On October 5, 1882, at a meeting of the Maryland College of Pharmacy, the following resolution to form a state association was produced:

> WHEREAS, the general progress and well-being of our profession demand that the Pharmacists everywhere be thoroughly organized, and
>
> WHEREAS, the business relations existing between Pharmacists and Wholesale and Manufacturing Druggists are and ought to be of the most intimate and confidential character, and
>
> WHEREAS, the Pharmacists, the Wholesale and the Manufacturing Druggists have thus far had no organization in this State for their mutual protection, benefit and the general advancement of pharmaceutical interests and knowledge:
>
> THEREFORE, BE IT RESOLVED, that a committee of fifteen be appointed to correspond with and invite every Pharmacist, Wholesale and Manufacturing Druggist in the State to meet in the city of Baltimore on the second Tuesday of May next to organize an association for the purposes set forth in the preamble.
>
> BE IT FURTHER RESOLVED, that the said committee be and are hereby instructed to draft a suitable Constitution and By-Laws, to be submitted to the proposed association for their consideration, and that they do such other work as will, in their judgement, be useful to, and facilitate the speedy organization of said proposed association.
>
> BE IT FURTHER RESOLVED, that we cordially tender to the Pharmacists, the Wholesale and the Manufacturing Druggists of the State the use of the College Building as a place of meeting.

In November 1882, the committee created by the resolution sent the following invitation to the pharmacists, chemists, and the wholesale and manufacturing druggists in the State:

> The undersigned Committee, acting in behalf of the Maryland College of Pharmacy, cordially invite you to meet in the city of Baltimore on the second Tuesday of May next at 11 o'clock A.M. at the hall of said college, for the purpose of organizing an Association of the Pharmacists, the Chemists, the Wholesale and the Manufacturing Druggists of the State, for the general advancement of the science of Pharmacy and the promotion of mutual interests. Be kind enough to advise the Committee if they may count upon your presence and hearty cooperation. Your attention is respectfully called to a series of resolutions under authority of which this call is issued.

The meeting was held on May 8, 1883, in the Hall at the Maryland College of Pharmacy. The resolutions, a draft constitution, and draft by-laws were presented to the attendees and subsequently approved. A slate of Officers was nominated, presented, and passed. The officers elected and committees established were as follows:

President: John J. Thomsen, Baltimore
1st Vice President: C. W. Crawford, Gaithersburg
2nd Vice President: Thomas. W. Shryer, Cumberland

Continued on page next page

Third Quarter 2018: Pharmacy Time Capsule

By: Dennis B. Worthen, PhD, Cincinnati, OH

1993

- ACPE released proposed standards and guidelines for the PharmD as the professional entry-level degree.
- New Mexico passed legislation to address a shortage of primary care providers making it the first state to let specially trained pharmacists provide primary patient care.

1968

- Fentanyl, developed by Janssen and marketed by McNeil, was approved as an IV analgesic.

1943

- *Bulletin of the American Society of Hospital Pharmacists* first published. Later renamed *American Journal of Health-System Pharmacy*.

1918

- Beginning of the Spanish flu pandemic.

1893

- New Mexico formed state pharmacy association.

One of a series contributed by the American Institute of the History of Pharmacy, a unique non-profit society dedicated to assuring that the contributions of your profession endure as a part of America's history. Membership offers the satisfaction of helping continue this work on behalf of pharmacy, and brings five or more historical publications to your door each year. To learn more, check out: www.aihp.org

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MPhA *Welcomes* OUR NEWEST MEMBERS

MARYLAND PHARMACISTS ASSOCIATION

Michael P. Ferris
Ilene Harris
Lisa Valerio Heber
Rajendra Kamma
Lisa Kao
Sapana Patel
Raj Pingili
Pamela Ann Piotrowski
Heidi Polek
Robert Rapier
Lauren Ru
Sheel Shah
Salem Shah
Judy Sim
Lindsay Wagner
Anna Marie Woods
Michael Yapp

History: How and When MPhA Was Formed *continued*

3rd Vice President: Hugh Duffy, Hillsboro
Secretary: John W. Geiger, Baltimore
Treasurer: E. Walton Russell, Baltimore
Executive Committee: Samuel Mansfield, Baltimore
Joseph B. Boyle, Westminster
Henry A. Elliott, Baltimore
Committees Established: Committee on Legislation
Committee on Pharmacy
Committee on Trade Interests
Committee on Business

Initially, there were 25 members who paid an initiation fee of $1.00 and annual dues of $2.00.

THE MARYLAND PHARMACEUTICAL ASSOCIATION WAS OFFICIALLY FORMED ON MAY 8, 1883, 135 YEARS AGO

Editorial

Spring Ahead in Your Pharmacy Career

By John Lee, PharmD Candidate 2019; Shelby Holstein, PharmD Candidate 2019; Patricia Dieso, PharmD Candidate 2019

On April 21, 2018, the pharmacy schools of Notre Dame of Maryland University (NDMU), the University of Maryland Baltimore (UMB), and the University of Maryland Eastern Shore (UMES) partnered with the Maryland Pharmacists Association (MPhA) to hold the second annual Spring Ahead in Your Pharmacy Career event. In the spring of 2017, these four groups originally partnered to create the novel event under the guidance of MPhA's Professional Development Committee, led by then-chairs, Dr. Amy Nathanson and Dr. Virginia Nguyen. The event was a significant undertaking, as it required constant communication and planning amongst all three pharmacy schools and MPhA. The efforts proved worthwhile. Student participants learned valuable lessons in email etiquette and conflict management and had ample opportunities for networking. The feedback from participants was so positive that the four groups chose to host the event again this year.

In its second year of planning, Maryland Schools of Pharmacy student representatives partnered with MPhA's Professional Development Committee, this year headed by Dr. Virginia Nguyen and Dr. Lynn Aung. After several months of discussion and planning, the event was revamped to feature two new topics reflective of Maryland student pharmacists' areas of interest. The first session was presented by Tim Baker of Script Financial. Mr. Baker covered the often overlooked, yet ever-important subject of managing student loans and debt, and discussed several financial management tips and strategies for students to consider when paying back their loans. The second new session featured Dr. Brandon Biggs of Kaiser Permanente, who presented a workshop on how to draft proper letters of intent. Every student pharmacist in the room, knowing they would have to write letters of intent in their near future, found this workshop positive and useful. Afterwards, students were treated to an APPE Student Panel led by the three-immediate past APhA-ASP Presidents in Maryland, and original collaborators of the Spring Ahead event, Tola Adebanjo, Rachel Lumish, and Mayrim Millan-Barea.

"What started as a pilot collaboration between the three schools of pharmacy, has now transformed into an annual event that benefits so many students. It is rare that students from all three schools come together, so I'm looking forward to seeing this professional development opportunity evolve each year," Rachel Lumish commented on the success of the event. Additionally, 12 practicing pharmacists in the Maryland area were present to meet with student attendees and conduct mock interview sessions. "As a student, it is encouraging to engage in mock interview sessions. The feedback that I received from the mock interview at MPhA will help me build better responses that reflect my strengths in future career interviews," attendee and 3rd year pharmacy student Stephanos Gozali noted.

The second annual collaborative event proved to yet again be a success. As student pharmacists in Maryland, it is rewarding to see the continual development and growth of our profession, and the collaborative efforts of all student pharmacists throughout the state work together. It is extremely encouraging to see the support and energy that Maryland pharmacists invest in student pharmacists for our professional development and preparation. Thank you to these mentors and the association — with your help, student pharmacists within MPhA are better prepared to be "Provider Ready."

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Charlene Chatzistrati
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Abidemi Dada
Harriet Daraja
Fritz Demanou
Lyndsay D'Intino
Linda Duong
Alyssia Dyett
Nahed Elias
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Kyle Gundlach
Quynh-Nhu Ha
Shannon Haar
Elliot Ho
Miaka Huynh
Fatemeh Khayatian
Thu Le
Farah Louzon
Sandrine Mbouyo
Mayrim Millan Barea
Ki Moon
Fortunate Mwanaka
Chibuike Nduanya
Binh Nguyen
Vy Nguyen
Phuong Nguyen
Uyen Nguyen
Muhammad Obaid
Jeffrey Oboite
Jasmine Offoha
Alexander Olumese
Michaela Palma
Sonya Park
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Constance Ambele
Rosa Ayele
Albert Ayernor
Etchi Awu Ayuk-Nkem
Manyo Ayuk
Scott Baker
Amber Benitez
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Raissa Fodjo
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Harris Ngokobi
Vu Nguyen
Terrance Nkunbuma
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Kamal Patel
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David Sproul
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Mesay Teklu
Thomas Tran
Shahrzad Vasy
Alberta Wacka

Tai Wang
Jessica Wearden
Winfield Whittington
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Michelle Alejandro
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Han Sol Yoo
SeJeong Yoon
Pamela Younes
Melissa Vanna Yuen
Victoria Luo Zhu

Class of 2018 *Outstanding Student Achievement Award Winners*

Tolani Adebanjo
University of Maryland Eastern Shore School of Pharmacy

Meryam Gharbi
University of Maryland School of Pharmacy

Miaka Huynh
Notre Dame of Maryland University School of Pharmacy

Save the Dates

For the most up-to-date schedule of MPhA activities visit www.marylandpharmacist.org. All activities are at MPhA headquarters unless otherwise indicated.

Sunday, September 16 — Do You Believe In MAGIC?

Notre Dame of Maryland University, Baltimore, MD

A one-day event designed for new practitioners and student pharmacists highlighting hot topics involving Mentorship, Advocacy, Growth, Innovation and Collaboration within the pharmacy profession.

Thursday, September 27 — Public Board of Trustees Meeting

Thursday, October 18 — Public Board of Trustees Meeting

Thursday, November 15 — Public Board of Trustees Meeting

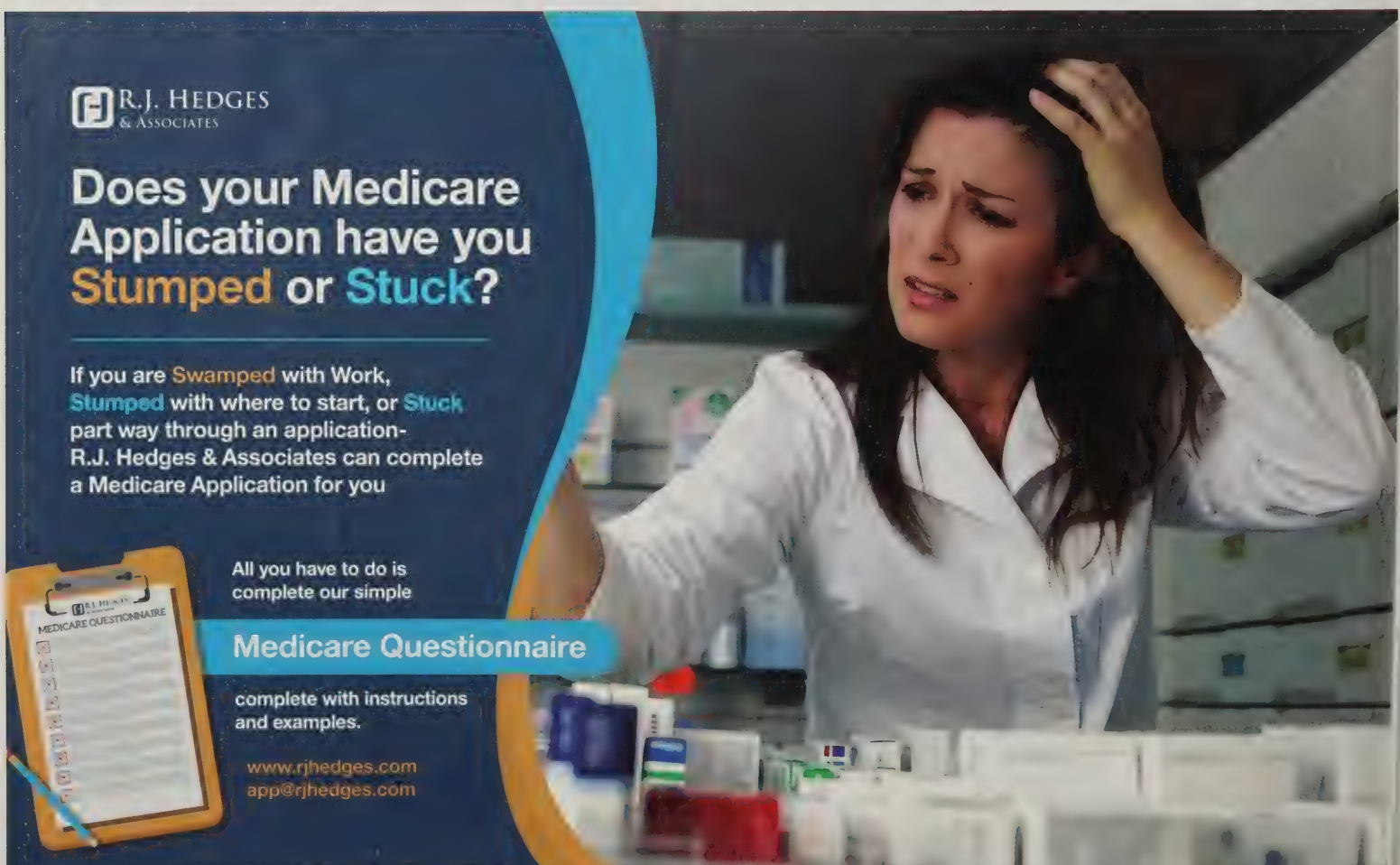
Thursday, December 13 — MPhA Holiday Party

Thursday, January 17, 2019 — Public Board of Trustees Meeting

Sunday, February 10, 2019 — 2019 MPhA Mid-Year Meeting

College Park Marriott Hotel and Conference Center, Hyattsville, MD

MPhA's annual one-day meeting for pharmacists, pharmacy technicians, and students from all practice settings. The meeting will feature hot topic continuing education sessions and networking opportunities.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Rx and the Law: Animal Patients

By Don R. McGuire Jr., R.Ph., J.D

The pharmacist at Anytown Pharmacy had prepared prescriptions for two pets and placed them in the refrigerator awaiting pickup. When Butch's owner came in to pick up his prescription, the owner was given another dog's prescription. Upon administration, the dog became lethargic and Butch's owner took him to the vet. Unfortunately, Butch's symptoms couldn't be reversed and he died as a result of the incorrect drug's effects. Butch's owner subsequently made a claim for damages against the pharmacy.

What damages is Butch's owner entitled to recover? In the majority of states, pets and other animals are considered personal property. As such, the owner is not entitled to recover damages for emotional pain and suffering or mental anguish, no matter how close the owner is to the pet or how much a part of their family they consider the pet to be. This can make these types of claims difficult to settle because the owner feels that the bond with their pet is not being considered. Under the law, they are correct. The bond with their pet is not compensable.

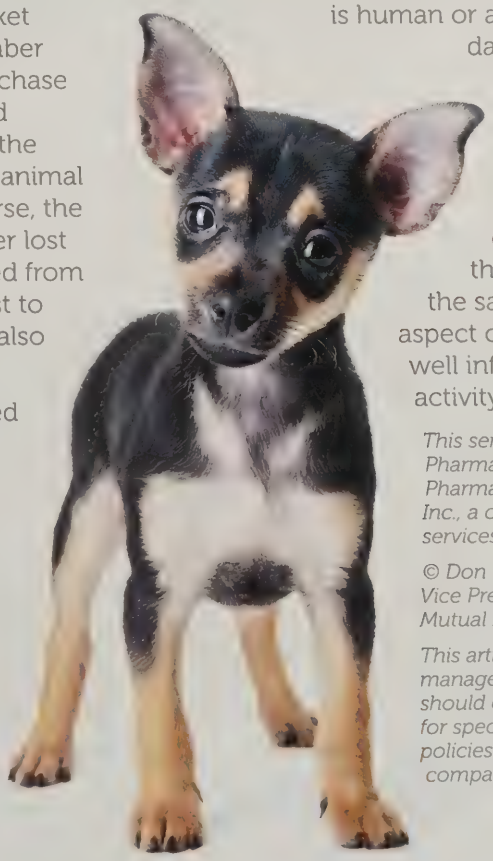
What is compensable is the market value of the animal and other costs resulting from the incident. These other costs could be the cost of treatment by a vet or in extreme cases, the cost of burial or cremation of the animal. The market value of an animal includes a number of factors, such as the original purchase price, the cost of replacement, and other elements that can enhance the animal's value. For example, if the animal patient is a prize-winning race horse, the owner would be entitled to recover lost stud fees and other income derived from the horse's performances. The cost to replace a winning race horse can also be substantial.

The potential vet bills for an injured pet could also be substantial. Because of the bond with their pet, the distraught owner might be willing to try any treatment, even those with only a small chance of success. It would not be unusual for vet bills to exceed the market value of an animal.

Because animals are considered property under the law, some states may have different procedures for these types of claims. States that have damage caps in medical negligence cases may not apply them here. These caps are generally applied to the injured patient's damages for pain and suffering. Because animal claims are property claims and there are no emotional damages, these caps do not apply. Also, because these claims are property claims, they may not be eligible for the Medical Review Panel process if that is in place in your state. In the Medical Review Panel process, the negligence claim is reviewed and evaluated by a panel of practitioners before the case can go to court. The case then only goes to court if one of the parties disagrees with the panel's decision.

Pharmacists may not think much about the financial risks from an animal claim because there are no damages for emotional distress. While this is true, the other exposures can still be significant. Market values for race horses that have died as the result of prescription errors can reach six figure settlements. This can be multiplied if more than one animal is killed or injured. A case in Florida in 2009 resulted in the deaths of 21 polo ponies from a compounded nutritional supplement. A jury awarded the owners of the horses $2.5 million.

Pharmacists are health care providers because they want to help their patients. This is true whether the patient is human or an animal. The differences in the law for damages as the result of an error should not influence the way that a pharmacist approaches the care that they provide. There are groups advocating in several states for changes in these laws to allow for the owner to recover emotional damages. Pharmacists will need to verify the law in their state. All patients deserve the same processes and safeguards. As with any aspect of their practices, pharmacists should be well informed of the standards and risks for any activity undertaken.



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© Don R. McGuire Jr., R.Ph., J.D., is General Counsel, Senior Vice President, Risk Management & Compliance at Pharmacists Mutual Insurance Company.

This article discusses general principles of law and risk management. It is not intended as legal advice. Pharmacists should consult their own attorneys and insurance companies for specific advice. Pharmacists should be familiar with policies and procedures of their employers and insurance companies, and act accordingly.

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Convention Wrap-Up

Thank you to all who attended MPhA's 136th Annual Convention in Ocean City, MD! And thank you to the Meeting Planning Committee, led by Darci Eubank and Sadhna Khatri, for putting together a great program of continuing education, networking, and fun!

RECOGNITIONS

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Cherokee Layson-Wolf, Chairman; Chai Wang, President; Richard DeBenedetto, Vice President; Mark Lapouraille, Treasurer; Betty Sanford, Honorary President

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2018 EXCELLENCE IN PHARMACY AWARDS

All winners and honorees are pictured with MPhA President, Cherokee Layson-Wolf.
Photography courtesy of Marci Strauss.

Bowl of Hygeia Award presented to Dixie Leikach, RPh, MBA, FACA

Honorary President Award presented to Betty Sanford, pictured with Mark Sanford, PD, RPh, MBA

Convention Wrap-Up *continued*

POLICY ACTIONS

The following policies were approved by the 2018 MPhA House of Delegates. A proposed policy on opioid dispensing was referred back to the committee for further refinement and will be brought back up at the 2019 Mid-Year Meeting. Thank you to the members of the Resolutions Committee: Matthew Balish, Chair and Richard Debenedetto, Ashley Moody, Hoai-An Truong, Jim Bresette, Chai Wang, Jim Dvorsky, Cherokee Layson-Wolf and students Adit Shah and Douglas Wienchedji.

Hepatitis C Treatment

Maryland Pharmacists Association supports the public health efforts for treatment and cure of Hepatitis C in all patients, regardless of stage of liver damage. Pharmacists are prepared to provide timely treatment, education and adherence support in order to ensure treatment cure.

Medication Disposal

Maryland Pharmacists Association supports access to all appropriate medication disposal efforts and education programs in order to reduce medication misuse. MPhA encourages pharmacists and pharmacies to provide medication disposal options and support medication disposal events. MPhA also encourages pharmacists and pharmacies to utilize all available resources to implement and expand education and disposal programs within pharmacies.

Pharmacists Rehabilitation Services

Maryland Pharmacists Association supports confidential referral to the contracted Maryland Board of Pharmacy Rehabilitation Services program for recovery and assistance for pharmacists, pharmacy technicians, and pharmacy students afflicted with a substance use disorder and encourages compliance with the duty to report requirement of the pharmacy practice act. Additionally, the Maryland Pharmacists Association supports legislation that will allow the Board of Pharmacy to support the operation programs that meet the needs of impaired pharmacists, pharmacy technicians and pharmacy students.

MPhA Mentor Award presented to Deanna Tran, PharmD, BCACP

Distinguished Young Pharmacist Award, sponsored by Pharmacists Mutual Companies, presented to Richard A. DeBenedetto, PharmD, MS, AAHIVP by Adam Pietlock, PhMIC Field Representative

MPhaA Seidman Distinguished Achievement Award presented to Joseph A. DeMino, PD

Shown at far right, Pharmacist Advocate Award, sponsored by Buy-Sell-A Pharmacy, presented to Surinder K. Singal, RPh, accepted on his behalf by Thomas Wieland, RPh

Shown at right, Excellence in Innovation Award, sponsored by Upsher-Smith Laboratories and the MPhA Foundation, presented to Jill A. Morgan, PharmD, BCPS, BCPPS

Cardinal Health Generation Rx Champions Award, sponsored by Cardinal Health Foundation, presented to Mary Lynn McPherson, PharmD, MA, MDE, BCPS, CPE by Leah Bonnes, Cardinal Health Representative

Outgoing Speaker of the House Recognition presented to Richard A. DeBenedetto, PharmD, MS, AAHIVP

Outgoing President Recognition presented to Cherokee Layson-Wolf, PharmD, CGP, BCACP, FAPhA presented by Chairman Kristen Fink

Outgoing MPhA Foundation President Recognition presented to Paul R. Holly, PD, BSPharm

Incoming President Recognition presented to James (Chai) Wang, PharmD, BCPS, AE-C

Outgoing Treasurer Recognition presented to Matthew G. Shimoda PharmD

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Continuing Ed

Chronic Obstructive Pulmonary Disease Treatment Update

Review of Recent Guideline Changes and Recommendations

Angeo Rey Belen, PharmD Candidate 2019, University of Maryland School of Pharmacy;
Kathleen J Pincus, PharmD, BCPS, University of Maryland School of Pharmacy

After completing this activity, the pharmacist will be able to:

1. Compare and contrast the updated 2011 and 2017 Global Initiative for Obstructive Lung Disease (GOLD) guidelines
2. Identify subjective and objective data used for assessment of chronic obstructive pulmonary disease (COPD)
3. Recognize medication classes central to treatment of COPD
4. Given a clinical case for a patient with COPD, select appropriate pharmacological treatment options for initial and step-up management

After completing this activity, the pharmacy technician will be able to:

1. Identify ways in which Global Initiative guidelines influence patient needs at the pharmacy level
2. Recognize medication classes central to treatment of COPD
3. Recognize potentially clinically significant information relative to COPD patients that should be referred to the pharmacist for consultation.

Keywords: chronic obstructive pulmonary disease, bronchodilators, inhaled corticosteroids

Introduction

Chronic obstructive pulmonary disease (COPD) is a progressive inflammatory lung disease characterized by obstructed airflow and respiratory symptoms such as shortness of breath and chronic cough. According to the World Health Organization, COPD is recognized as the fourth leading cause of death in the world with 3.2 million lives claimed in 2015.[1] Within the United States, COPD has been diagnosed in more than 15.7 million Americans and stands as the primary contributor to chronic lower respiratory disease, a leading cause of death in the country.[2,3] The Global Initiative for Obstructive Lung Disease (GOLD) has published reports based on scientific literature which guide the diagnosis, assessment, and treatment of COPD. While the 2011 GOLD Report received yearly updates from 2013 to 2016, the treatment paradigm remained mostly unchanged.[4] Then in November 2016, GOLD published its 2017 report which includes changes to severity assessment and treatment recommendations.[5] This article will review the updated guidelines and discuss selection between treatment options.

Pathophysiology

COPD is characterized by chronic inflammation, increased presence of inflammatory cells within the lungs, and structural damage to the pulmonary system. Cigarette smoking or exposure to other noxious particles such as chemical fumes or air pollution can trigger inflammatory processes in the lungs leading to development of these pathologies. This structural damage leads to decreased expiratory capacity and trapping of gases in the lungs. The resulting hyperinflation of the lungs combined with altered pulmonary function, leads to shortness of breath, the most common symptom of COPD.

Assessment

Airflow Limitation

Due to its noninvasiveness, reproducibility, and availability, spirometry is used by the updated 2011 and 2017 GOLD guidelines as the standard objective measurement of airflow limitation in COPD patients. Spirometry measures the volume of air forcibly exhaled after maximal inspiration (forced vital capacity, FVC) and the volume of air forcibly exhaled during the first second of this maneuver (forced expiratory volume in one second, FEV1). These values can be measured after administration of a bronchodilator such as a short-acting beta2-agonist, a short-acting anticholinergic, or a combination of the two. The chronic inflammation and narrowing of the peripheral airways in the lungs results in a decreased FEV1 and FEV1/FVC ratio. More specifically, a calculated post-bronchodilator ratio of FEV1/FVC < 0.70 confirms the presence of airflow limitation per the GOLD guidelines.

While this result is necessary to clinically diagnose COPD, both versions of the GOLD guidelines recommend using symptoms and exacerbations as additional parameters for diagnosis. Indeed, a study published after the 2011 GOLD guidelines were released showed poor correlation between

lung function, symptoms, and exacerbation frequency.[6] In addition, the results of spirometry can be affected by patient-specific factors such as age and location. For example, a study focusing on elderly patients aged ≥ 65 years found that using an FEV1/FVC < 0.70 as the sole diagnostic criterion led to over-diagnosis of COPD.[7] Another study found that after adjusting for height, age, and sex, FEV1 values can differ substantially between global regions, further impacting COPD classification and management in various geographical areas.[8] Regardless, both the updated 2011 and 2017 GOLD guidelines recommend using the post-bronchodilator FEV1 cut-off values given in Table 1 to classify patients into GOLD grade 1 – 4 based on the severity of airflow limitation.

Symptoms

Dyspnea, or shortness of breath, is one of the most common symptoms in COPD and is associated with increased disease severity, increased risk of COPD exacerbation, and increased risk of mortality in a severity-dependent manner.[9-10] Thus, due to its significance, both versions of the GOLD guidelines recognize the value of assessing breathlessness in COPD. More specifically, the Modified British Medical Research Council Questionnaire (mMRC) is discussed in the guidelines as a way for patients to rate their sensation of breathlessness. mMRC grading can range from 0 to 4 with a higher grade corresponding to increased impact of breathlessness on patient quality of life.

Another tool discussed in both guidelines that more comprehensively assesses the impact of COPD on patient health status is the COPD Assessment Test (CAT). This 8-item instrument has been discussed in multiple publications as a widely-available and simple tool for clinicians to predict risk of exacerbation, deterioration of health status, depression, and mortality in COPD patients.[11] CAT scores can range from 0 to 40 with a higher score corresponding to increased health status impact. Ultimately, CAT scores do not correspond with mMRC grades and vice-versa, though both are useful for objectively characterizing the severity of COPD symptoms. Both screening tools are available on the GOLD website at https://goldcopd.org.

Other common symptoms seen in COPD include chronic cough (usually the first symptom), wheezing, chest tightness, and sputum production. As the disease progresses and becomes more severe, additional symptoms include fatigue, weight loss, and anorexia. However, these more severe symptoms can be caused by other diseases and should be investigated.

Exacerbation Risk

Both versions of the guidelines define COPD exacerbation as an acute worsening of respiratory symptoms which leads to medication changes. Exacerbations can be caused by infections, air pollutants, or be idiopathic in nature. A recent literature review found that COPD exacerbations can be linked to short- and long-term clinical implications including accelerated lung function decline, decreased quality of life, and even increased risk of death.[12] Interestingly, studies have found that one of the strongest predictors for future COPD exacerbation is prior history of exacerbations. Thus, exacerbation history is an important consideration for exacerbation risk and overall COPD severity.[13-15]

Combined COPD Assessment

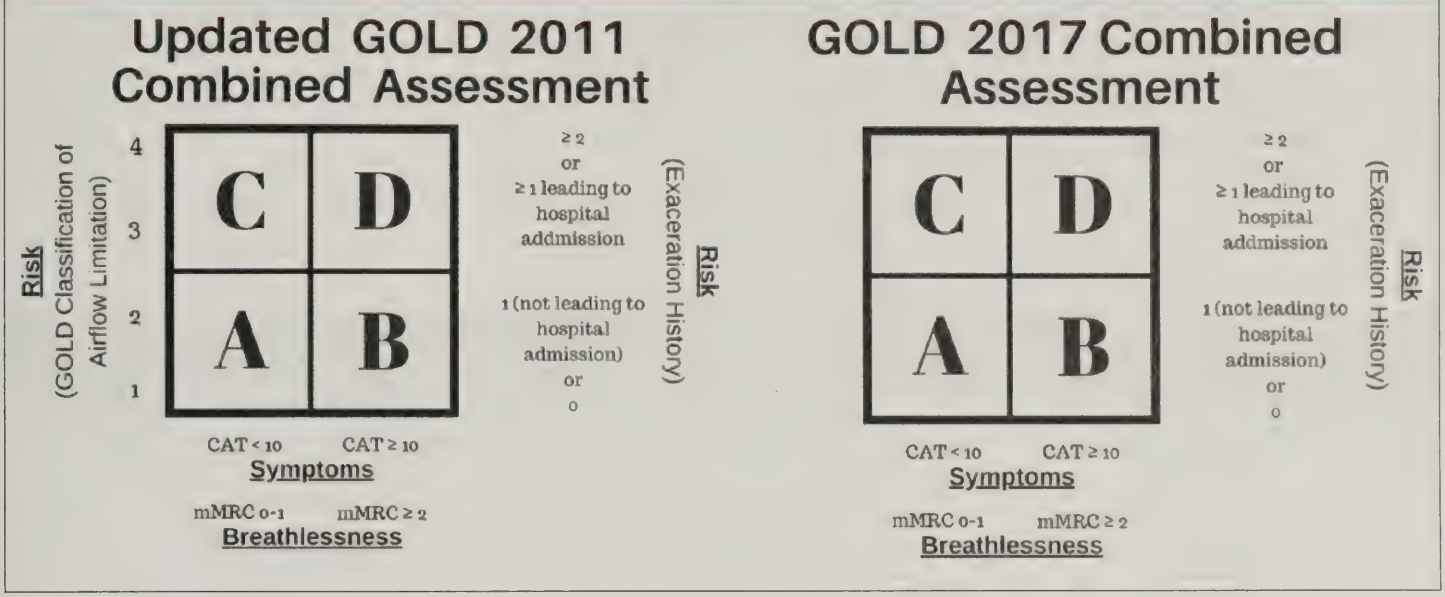
As discussed, spirometry data and clinical symptoms should both be used when assessing COPD status in a patient: spirometry allows for an objective assessment of lung function while symptoms allow for a subjective assessment of clinical impact. With the release of the 2011 GOLD guidelines, both types of data were used to classify patients in an "ABCD" system which corresponded to COPD severity. Within the system, group A is considered the least severe and group D the most severe of the four groups. However, the 2011 and 2017 guidelines begin to diverge when discussing how spirometry should be incorporated.

Within the 2011 guidelines and its subsequent updates until 2016, if post-bronchodilator FEV1 values are available to classify patients into GOLD grade 1 – 4, this grading can then be used as a predictor of COPD exacerbation risk: GOLD grade 1 and 2 patients have low risk for exacerbation and GOLD grade 3 and 4 patients have high risk for exacerbation. If this spirometry value is not available, exacerbation risk can also be predicted using the patient's history of exacerbations within the past year: 0 or 1 exacerbation not leading to hospital admission is considered low risk while ≥ 2 exacerbations or ≥ 1

Table 1: Airflow Limitation Severity Classification in COPD Based on Post-Bronchodilator FEV¬$_1$

In patients with FEV1/FVC < 0.70:		
GOLD 1	Mild	FEV_1 ≥ 80% predicted
GOLD 2	Moderate	50% ≤ FEV¬$_1$ ≤ 80% predicted
GOLD 3	Severe	30% ≤ FEV¬$_1$ ≤ 50% predicted
GOLD 4	Very Severe	FEV_1 < 30% predicted

Figure 1: Combined COPD Assessment Based on the 2011 and 2017 Guidelines



exacerbation leading to hospital admission is considered high risk. If risk assessment leads to conflicting results (for example, low risk via GOLD grading and high risk via exacerbation history), the higher risk is chosen.

In addition to risk assessment, symptom assessment using mMRC grading or CAT scores can be used to determine symptom burden: a CAT score < 10 or a mMRC grading of 0 to 1 is considered low symptom burden while a CAT score ≥ 10 or a mMRC grading ≥ 2 is considered high symptom burden. Risk assessment and symptom assessment are then combined to assign patients into GOLD group A – D. To summarize, assessment of a COPD patient involves assigning a number which corresponds to airflow limitation and a letter which corresponds to symptom burden and exacerbation risk. For example, a patient with FEV1 of 40% predicted who has had zero COPD exacerbations in the past year and a CAT score of 15 would be considered GOLD grade 3 group C per the 2011 version of the guidelines.

However, using this ABCD classification system established by the 2011 GOLD guidelines was found to be a minimal improvement over using spirometry data to assess lung function decline and mortality.[16-18] In addition, statistically significant differences in GOLD grade categorization were seen in grade D patients depending on whether exacerbation risk was assessed based on spirometry values, exacerbation history, or both.[6] This difference highlights the variability that can occur in category assignment when either of these parameters can be used. Thus, the 2017 guidelines revised the system by separating spirometry from the "ABCD" system.

Within the 2017 guidelines, the FEV1/FVC ratio is still used to diagnose COPD, and the FEV1 value is still used to assess the severity of airflow limitation by classifying patients into GOLD grade 1 – 4. However, as seen in Figure 1, while CAT and mMRC scores can still be used, the GOLD 1 – 4 grading is now no longer incorporated into assignment within one of the four ABCD groups. While spirometry is still recommended for these patients, the 2017 combined COPD assessment scheme prioritizes assessment of symptoms and exacerbation history only. Ultimately, assuming the necessary data is available, patients are still assigned a GOLD grade 1 – 4 and a GOLD group A, B, C, or D. For example, a patient with FEV1 of 40% predicted who has had zero COPD exacerbations in the past year and a CAT score of 15 would now be considered GOLD grade 3 group A per the 2017 version of the guidelines.

Pharmacologic Treatment

Both versions of the guidelines list three therapeutic objectives when using pharmacologic therapy: (1) reduce symptoms; (2) reduce the frequency and severity of exacerbations; and (3) improve health status and exercise tolerance. Both guidelines also list bronchodilators as the central treatment for COPD patients. These medications relax airway smooth muscle tone and thus improve inspiratory capacity which can improve exercise tolerance and make it easier for patients to breathe.[19] Two classes of bronchodilators are recommended:

beta2-agonists and muscarinic receptor antagonists. Medications in each class commonly used for COPD management are listed in Table 2. While methylxanthines are briefly discussed in both guidelines as a third class of bronchodilators, their limited data and wide range of toxicities have limited their use.

Beta2-agonists are available as short-acting (SABA) or long-acting (LABA) formulations. This class of medications binds to beta2 adrenergic receptors present in airway smooth muscle cells, activating a cascade involving cyclic adenosine monophosphate (cAMP), protein kinase A, and phosphorylation of targets which mediate smooth muscle relaxation.[20] Adverse effects include cardiac rhythm disturbances and somatic tremor.[20]

Muscarinic receptor antagonists are also available as short-acting (SAMA) or long-acting (LAMA) formulations. This class of medications blocks muscarinic receptors in the airways which mediate bronchial smooth

Table 2: Common Medications Used in COPD

Beta$_2$-agonists	
Short-acting	**Long-acting**
levalbuterol (Xopenex®)	arformoterol (Brovana®)
salbutamol (albuterol) (Proventil®, Ventolin®)	formoterol (Perforomist®)
terbutaline (Brethine®)	indacaterol (Arcapta Neohaler®)
	olodaterol (Striverdi Respimat®)
	salmeterol (Serevent®)
Muscarinic receptor antagonists	
Short-acting	**Long-acting**
ipratropium bromide (Atrovent®)	aclidinium bromide (Tudorza ®)
	glycopyrronium bromide (Seebri Neohaler®)
	tiotropium (Spiriva®, Spiriva Respimat®)
	umeclidinium (Incruse Ellipta®)
Combination short-acting beta$_2$-agonist + short-acting muscarinic receptor antagonist	
fenoterol + ipratropium (Duovent®)	
salbutamol (albuterol) + ipratropium (Combivent®, Duoneb®)	
Combination long-acting beta$_2$-agonist + long-acting muscarinic receptor antagonist	
formoterol + glycopyrronium (Bevespi Aerosphere®)	
indacaterol + glycopyrronium (Utibron Neohaler®)	
olodaterol + tiotropium (Stiolto Respimat®)	
vilanterol + umeclidinium (Anoro Ellipta®)	
Combination long-acting beta$_2$-agonist + inhaled corticosteroid	
formoterol + beclomethasone	
formoterol + budesonide (Symbicort®)	
formoterol + mometasone (Dulera®)	
salmeterol + fluticasone (Advair®)	
vilanterol + fluticasone (Breo Ellipta®)	
Combination long-acting beta$_2$-agonist + long-acting muscarinic receptor antagonist + inhaled corticosteroid	
Vilanterol + umeclidinium + fluticasone (Trelegy Ellipta®)	

muscle contraction and mucus release.[20] Adverse effects include anticholinergic effects, mainly dry mouth and throat irritation.[20] Certain medications in this class may also cause upper respiratory infections.

In addition to bronchodilators, both guidelines also discuss the use of inhaled corticosteroids (ICS) as an additional treatment option for certain GOLD groups. This class of medications activates specific glucocorticoid receptors and downregulates inflammatory response.[20] A 2012 Cochrane review concluded that while ICS can reduce the decline in quality of life and frequency of exacerbations, these medications also increase the risk of oral candidiasis, throat hoarseness, and pneumonia.[21] However, the large-scale SUMMIT trial found no excess risk of pneumonia in moderate COPD patients.[22] Thus, the benefits of ICS must be carefully weighed against their risk.

In general, short-acting agents are preferred for symptom rescue on an as-needed basis while long-acting agents are preferred for maintenance therapy. Co-formulations for certain SABA + SAMA and LABA+LAMA combinations are also available. Studies and meta-analyses have not shown conclusive mortality benefits with ICS monotherapy.[21] Thus, both guidelines do not recommend treatment with ICS alone. Table 2 outlines common co-formulations involving an ICS. Ultimately, regimens should be based on symptom severity, degree of airflow limitation, and patient responsiveness and preference.

Both the updated 2011 and 2017 GOLD guidelines make recommendations for first-line initial therapy based on GOLD group; however, there are differences between the two:

- For group A patients, the updated 2011 guidelines recommend a

ACTIVE LEARNING – PATIENT CASE

AB is a 56 year old Caucasian male with a 12-year history of COPD. He currently takes one inhalation of Advair Diskus 250 / 50 (250 mcg fluticasone propionate + salmeterol 50 mcg) twice daily with no apparent issues in technique. During his visit to the ambulatory care clinic, he reports having increased shortness of breath, wheezing, coughing, and clear sputum production which has been getting worse over the past few months. His mMRC score is 3. He has had two COPD exacerbations in the past year, both of which have required hospitalization. He was also recently discharged from the hospital for pneumonia and is concerned about a recurrence. Other past medical history includes asthma and diabetes. Patient is a former smoker and denies alcohol or recreational drug use.

1. Based on the 2017 GOLD guidelines, AB would be classified under which GOLD group?
   a. GOLD group A
   b. GOLD group B
   c. GOLD group C
   d. GOLD group D
2. Based on your GOLD group assignment, which of the following would be an appropriate escalation strategy for the pharmacologic management of AB's COPD?
   a. Addition of albuterol
   b. Addition of salmeterol
   c. Addition of umeclidinium
   d. Switch to umeclidinium + vilanterol
3. AB was subsequently started on tiotropium. He should be counseled on which of the following adverse effects of this medication?
   a. Dry mouth
   b. Tremor
   c. Increased risk of pneumonia
   d. Oral candidiasis
4. One year later, AB presents to your clinic with additional symptoms. He is currently taking tiotropium and fluticasone propionate + salmeterol but was hospitalized for a COPD exacerbation one month ago. His most recent FEV1 is 32% predicted with no change in chronic cough or wheezing. Which of the following would be appropriate options for AB's pharmacologic treatment?
   a. Addition of roflumilast
   b. Addition of macrolide antibiotic
   c. Removal of tiotropium
   d. Removal of salmeterol

Answers on page 24

short-acting bronchodilator (SABA or SAMA). The 2017 guidelines recommend a short-acting (SABA or SAMA) or long-acting (LABA or LAMA) bronchodilator.

- For group B patients, both versions of the guidelines recommend a long-acting bronchodilator (LABA or LAMA).
- For group C patients, the updated 2011 guidelines recommend a combination ICS + LABA or ICS + LAMA. The 2017 guidelines recommend LAMA monotherapy.
- For group D patients, the updated 2011 guidelines recommend a combination ICS + LABA or ICS + LAMA. The 2017 guidelines recommend a combination LABA + LAMA or LABA + ICS. Alternatively, if a single agent is preferred, LAMA monotherapy is recommended.

Because COPD patients are likely to return with persistent or worsening symptoms, the 2017 GOLD guidelines added a proposed treatment algorithm for subsequent escalation or de-escalation of pharmacologic treatment. For persistent symptoms or further exacerbations requiring escalation of therapy, the following recommendations are made:

- For group A patients, an alternative class of bronchodilators can be considered.
- For group B patients, the use of two long-acting bronchodilators is preferred (LABA + LAMA).
- For group C patients, the use of two long-acting bronchodilators is preferred (LABA + LAMA). Alternatively, a LABA + ICS can be considered.
- For group D patients on monotherapy, the use of two long-acting bronchodilators is preferred (LABA + LAMA). A LABA + ICS can also be considered as an alternative. For patients already on dual therapy, a triple regimen of LABA + LAMA + ICS is preferred. Further exacerbations after triple therapy involves consideration of a macrolide in former smokers or consideration of roflumilast if FEV is < 50% predicted and the patient has chronic bronchitis. If de-escalation from triple therapy is warranted, the ICS should be removed initially based on lack of efficacy or concern for adverse effects (including pneumonia).

However, the 2017 guidelines note that while these recommendations were based on available efficacy and safety data, further research is needed as treatment escalation had not been systematically tested and treatment de-escalation was based on limited data and included only ICS.

LABA versus LAMA

Within the updated 2011 guidelines, no distinction is made when considering whether to start with a LABA or LAMA. However, many of the current LAMAs have come to market since the initial 2011 guidelines. Subsequent updates, especially the 2017 guidelines, have reflected the evolution of approval, data, and clinical effects regarding muscarinic antagonists. While both medication classes are still recommended in the 2017 guidelines based on their similarities in symptom and lung function improvement, a LAMA (tiotropium) is now preferred over LABA based on greater decreases in COPD exacerbations leading to hospitalization, serious adverse events, and exacerbation rates.[23] This may be especially true in patients with pre-existing cardiac rhythm disturbances or tremor as a LABA can aggravate these conditions.

LABA + LAMA versus LABA + ICS

Transitioning from the updated 2011 to the 2017 GOLD guidelines, ICS have taken a less prominent role. More specifically, a LABA + LAMA combination is the preferred regimen with ICS addition being considered an alternative or as part

ANSWERS

1. **Answer: D** Based on the patient's history of > 2 exacerbations he would qualify for groups C or D (Answers A and B are incorrect). Given his mMRC score > 2 he is best classified as Group D (Answer C incorrect).
2. **Answer: B** Currently the patient's regimen includes a combination LABA + ICS. For Group D patients already on dual therapy, the GOLD guidelines recommend a triple regimen of LABA + LAMA + ICS if escalation is necessary based on persistent symptoms. Addition of a SABA such as albuterol, an additional LABA such as salmeterol, or switching to a LAMA + LABA combination such as umeclidinium + vilanterol would not be warranted (Answers A, B, and D are incorrect). Of the available options, addition of a LAMA such as umeclidinium is the only way to achieve the recommended triple therapy (Answer C is correct).
3. **Answer: A** Tiotropium is a LAMA. Anticholinergic effects such as dry mouth are a common adverse effect within muscarinic receptor antagonists (Answer A is correct). Tremors are uncommon for LAMAs; rather, they are more common in beta2-agonists (Answer B is incorrect). Increased risk of pneumonia and oral candidiasis are also uncommon for LAMAs; rather, they are more common in ICS (Answers C and D are incorrect).
4. **Answer: A and B.** For GOLD Group D patients already on LABA + LAMA + ICS triple therapy but requiring an escalation of therapy, addition of macrolides can be considered in former smokers and addition of roflumilast can be considered in patients with chronic bronchitis and an FEV < 50% predicted. Since this patient fits these criteria, he would be a candidate for either therapy (Answers A and B are correct). Removal of a LAMA (e.g. tiotropium) or a LABA (e.g. salmeterol) in response to persistent symptoms or an exacerbation is not recommended by the GOLD guidelines (Answers C and D are incorrect).

of triple therapy. Systematic reviews and meta-analyses have shown that when compared to LABA + ICS, a LABA + LAMA combination was associated with lower risks of exacerbation and pneumonia and larger improvements in FEV1 and quality of life.[24-26] However, a meta-analysis has shown that patients with increased blood eosinophil count may have increased response to treatments involving ICS.[27] Thus, ICS treatment may be preferred in patients with such a biomarker or in patients with a comorbidity that increases eosinophil count such as asthma.

Triple Therapy (LABA + LAMA + ICS)

Both versions of the guidelines discuss triple therapy as a consideration in GOLD group D patients after failure of dual therapy. However, current evidence regarding triple therapy is limited: while there is evidence for improved outcomes in triple therapy over LABA + ICS and LAMA monotherapy, the regimen's efficacy compared to LABA + LAMA is still largely unknown.[28] However, studies are ongoing, and a study published in May 2018 showed triple therapy with fluticasone furoate + umeclidinium + vilanterol resulted in a lower rate of COPD exacerbations than dual therapy with fluticasone furoate + vilanterol or umeclidinium + vilanterol.[29] In addition, the United States Food and Drug Administration recently approved this triple combination (Trelegy Ellipta, GlaxoSmithKline and Innoviva) in September 2017 as the first once-daily single inhaler triple therapy for COPD.

The Pharmacist's Role

Beyond medication recommendations, pharmacists can play a pivotal role in the management of this disease state. For example, regardless of whether a patient is in an inpatient or outpatient setting, appropriate education on inhaler technique and use is crucial to successful treatment and minimization of adverse effects. In addition, for patients with coordination impairments, inspiratory limitations, or complaints of unpleasant taste or sore throat, the potential use of a spacer can be assessed by a pharmacist. Finally, pharmacists can provide patients with appropriate monitoring parameters and counseling points for proper inhaler technique, symptoms and adverse effects. This is especially important as the guidelines emphasize the importance of reinforcing proper inhaler technique and ability at every transition of care or interaction with a healthcare professional. For example, having an individualized exacerbation action plan can be helpful for emergency preparedness and rinsing one's mouth with water after use of an inhaler containing an ICS can be useful for preventing oral candidiasis. Both points can be made by a pharmacist during routine medication counseling in addition to discussing the importance and benefits of smoking cessation and appropriate vaccinations (influenza and pneumococcal) in these patients.

Conclusion

The GOLD guidelines offer guidance on COPD treatment; however, assessment and treatment recommendations have changed between the updated 2011 guidelines and the 2017 guidelines. While

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subjective and objective data are necessary for disease assessment, GOLD grading 1 – 4 based on airflow limitation has been separated from GOLD grouping A – D. Furthermore, the new guidelines consider inhaled corticosteroids as alternative treatment compared to bronchodilators, especially when considering the proposed algorithm for escalation and de-escalation of therapy.

Pharmacists need to stay updated with the most recent data and guidelines to ensure optimal medication recommendations. Ongoing studies seek to further refine initial recommendations and escalation strategies for COPD. Ultimately treatment of COPD, as in other disease states, must be personalized as patient preferences, clinical presentation, and disease progression are unique to each individual.

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Executive Director's Message

Thank you everyone who joined us in Ocean City for our 136th Annual Convention. We were back at the beach with a great cast of old friends and new. It was awesome to see many people who had never attended an MPhA meeting, show up and make connections. I am so pleased that many of you have said you'll be back!

We certainly benefitted from a line-up of fantastic speakers, who hit on clinical, professional and personal topics. And of course the great weather! We incorporated new program features and maintained many of your favorites. As we look at this meeting compared to our last time in Ocean City:

- We increased the number of CEs offered at the meeting and included an opportunity for CPR classes; and
- Increased the overall meeting attendance – that increase included a good number of first-time attendees. We thank all of you for making them feel welcome.

As I think back on the meeting, what resonated with me was a theme of recognition. We had an opportunity to recognize so many of the great things happening at MPhA and where we need to focus on the future:

- The accomplishments, leadership and service of many of our pharmacy colleagues and MPhA leaders;
- The roles and opportunities for pharmacists to play in addressing the healthcare needs of patients and in reducing the impact of healthcare costs in the state of Maryland;
- New partners to advance our mission and policy objectives;
- The long-term commitment of our members, many who have attended the Annual Convention for more than 40 years, and the enthusiasm of those who are newly engaged with MPhA; and
- The profession's challenges with the opioid epidemic and workplace stresses.

The convention was a busy several days! It was wonderful to see so many of you! I hope you found time to unwind a bit and engage in fun activities or just relax with friends and/or family. As we head into Fall, I urge you to continue to find ways to take a break, to replenish your mind, body and spirit. It is important for your self-care and for the service you provide to so many who need you!

Aliyah N. Horton, CAE
Executive Director

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Maryland Pharmacist

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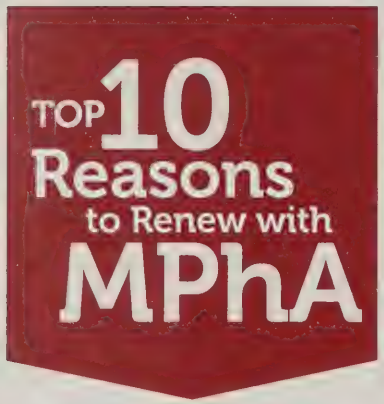

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Aliyah N. Horton, CAE, Executive Director
Lauren Williams, Director of Programs and Membership Engagement
Shawn Collins, Membership Services Coordinator

CONTRIBUTORS
NASPA Services Company, LLC, Editorial
Katy Pincus, PharmD, BCPS
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Maryland Pharmacists Association, 9115 Guilford Road, Suite 200, Columbia, MD 21046, call 443.583.8000, or email aliyah.horton@mdpha.com.

President's Pad

Dear MPhA Members,

In the previous journal, I shared my vision for shaping the future of the association through our theme of "Imagineering: Transforming MPhA Through Innovation." Imagineers, from our refreshed committee leadership and Trustees to our Past Presidents, have already taken initiative in creatively identifying opportunities to increase member engagement and value. Although we are just starting the year, I would like to provide a brief update on our progress.

Our committees, refreshed with new leadership and supported by our past presidents, are already convening regular meetings and targeting their charges for the year. From developing sustainable committee infrastructure to planning activities which promote member value, they are embracing the call to innovate. Notably, our professional development committee recently unveiled a new addition to our membership value proposition. Through this event titled "Do You Believe in MAGIC?," student pharmacists and new practitioners participated in interactive seminars and workshops focused on developing skills for navigating change, capitalizing on networking opportunities, and innovating in the workplace. I also shared membership opportunities and highlighted the value of being engaged with the association. For those of you who missed the event, please be on the lookout for future recordings of select sessions as part of your membership benefits.

Through developing sustainable committee infrastructure to planning activities which promote member value, our committees are poised to expand offerings and to increase membership value to continue to transform "MPhA through innovation."

The Board has also been hard at work preparing for the upcoming year. In late August, we convened the annual board orientation and discussed opportunities to increase member engagement. We also focused on exploring infrastructure improvements and expressed an interest to promote social events for direct member engagement. At future board meetings, the Board will be reviewing various proposals to improve access to the association and increase membership value. These changes may be necessary to take our association to the next level, and any Board decision will be carefully considered and shared with the membership. We welcome your input and encourage you to contact the association office anytime.

To ensure future continuity, I have placed an emphasis on strengthening our member infrastructure this year. As part of this initiative, I am focused on increasing opportunities for member representation. Our resolutions committee will be developing a process for selecting Maryland delegates to the APhA House of Delegates, and our advocacy committee is already evaluating potential legislative priorities which will improve pharmacy practice. In addition, I am interested in increasing support and representation for our members residing or working in

Letter to the Editor

To the Editor:

I read with interest the article "The Role of Professional Pharmacy Organizations and Its Impact on the Profession of Pharmacy" written by Howard University College of Pharmacy and MPhA Rotation Student Enaefe Ziregbe, published in the Spring 2018 edition of the *Maryland Pharmacist*. Ms. Ziregbe examines and emphasizes the mission, importance, and intrinsic value of professional pharmaceutical organizations including the American Society of Hospital Pharmacists, the American Association of Colleges of Pharmacy, the American Pharmacists Association, the National Community Pharmacists Association, the Academy of Managed Care Pharmacy, and the Maryland Pharmacy Coalition. She expands and intensively describes the role of the Maryland Pharmacists Association in promoting the pharmacy profession and the interests of Maryland pharmacists through political awareness and action, continuing education annual meetings, monthly organizational meetings, statewide outreach, and student involvement in the three pharmacy schools operating within the state of Maryland.

However, I feel that Ms. Ziregbe has omitted one very significant and salient category available to pharmacists, namely the pharmacy fraternities. These societies, almost always co-ed, provide male and female pharmacy students the possibility of interacting with like-minded classmates in professional and social extracurricular environs. In the realm of pharmacy school studies and demands, the rituals and essential unwinding among friends and counterparts can be therapeutic and reviving.

I can write of my own experiences in pledging the Kappa Chapter of the Alpha Zeta Omega Pharmaceutical Fraternity (AZO) at the University of Maryland School of Pharmacy, and ultimately being ceremoniously initiated into Kappa Chapter. I relished the collective interactions with companionable undergraduate aspirants of the pharmacy degree, detached from the academic institution's administration. Following graduation, I became active in the alumni AZO chapter which has remained a source of professional enlightenment, camaraderie, fun, and occupational fulfillment. The monthly chapter meetings have afforded me the opportunity to remain in contact with fraternity brothers I have known since college days and to be enriched by the influx of new, younger inductees. The biannual conventions enable Kappa fraters to socially and professionally interact with other AZO fraters from the many other chapters.

Considering how I personally have benefitted from belonging to a pharmacy fraternity, by extension I strongly contend that pharmacy fraternities deserve to be included among the stalwart associations that Ms. Ziregbe itemizes.

Respectfully submitted,

Melvin Lessing, P.D., M.S., MPhA Member
Assistant Editor, *Military Medicine*

President's Pad *continued*

Western Maryland and Eastern Shore. By exploring the possibility of regional interest groups, I hope to further engage members who may not be able to travel great distances to participate in association activities.

Finally, you may have already received your renewal notice for membership for 2019. If you have already renewed, we greatly appreciate and thank you for your continued support. If you have not yet done so, we hope you will join us this upcoming year. We are excited about our expanded offerings to increase membership value, and I encourage you to participate in our activities as we continue to transform "MPhA through Innovation." I hope you will look forward to future invitations through the Monday Message and our social media communications.

Thank you for reading, and I look forward to sharing additional updates in our next journal.

Chai Wang, PharmD, BCPS, AE-C
President, Maryland Pharmacists Association 2018-2019

Member Mentions & News You Can Use

American Pharmacists Month

American Pharmacists Month is a time to recognize pharmacists' contributions to health care and all you can do for the community. We hope you'll get involved in the campaign to spread the word about your vital role as a member of the health care team and a provider of patient care services. Please visit www.marylandpharmacists.org to find many resources and ideas for how you can participate in and celebrate throughout October.

APhM
American Pharmacists Month
Easy to Reach, Ready to Help

Pharmacy Technician Day

October 16, 2018 is Pharmacy Technician Day and is an opportunity to recognize the invaluable contributions technicians make in all practice settings throughout the year. ***Urge your pharmacy to purchase memberships in MPhA for technicians this month.***

Pharmacists: Take a moment this month to acknowledge the work of the technicians at your practice site and thank them for all they do for you and your patients.

Pharmacy technicians: Promote American Pharmacists Month with your fellow technicians and pharmacists in your practice setting! For additional information including content and social media images, go to www.ptcb.org.

#RxTechDay
PHARMACY TECHNICIAN DAY
TUESDAY, OCTOBER 16, 2018
Celebrating the Essential Role of the Pharmacy Technician

MPhA on the National Stage

MPhA Executive Director Aliyah N. Horton, CAE, participated in a panel discussion with national healthcare CEOs at the American Society for Association Executives (ASAE) 2018 Annual Convention, entitled "A View from the Top." Horton discussed her career trajectory as well as the importance of bipartisan advocacy, collaboration amongst healthcare stakeholders for the betterment of patients, PBM transparency, creating opportunities for practice advancement and pharmacist well-being.

MPhA Participation Opioid Use Disorders Roundtable Discussion

MPhA leadership participated in a pharmacy roundtable discussion hosted by the University of Maryland School of Pharmacy and the Behavioral Health Administration (BHA) focused on efforts to engage pharmacists to address Maryland's opioid crisis. BHA recognized the important role that pharmacists play in expanding access to care for patients with opioid use disorder. They are funding a project to identify and resolve the barriers that pharmacists face in managing patients with this disorder. Past and present MPhA leaders and members participated in the discussion to provide their perspective and input on pharmacist roles, barriers they face, naloxone dispensing, medication assisted treatment, approaches that pharmacies have instituted and opportunities for the profession. The pharmacy voice and involvement are critical to reducing overdose deaths, promoting successful treatment and developing strategies to prevent the complications of opioid misuse.

Advocacy and Engagement

MPhA continues participation in the stakeholder working group working on pharmacists **contraceptive prescriptive authority**. Final regulations related to the prescriptive authority were published in the June 22 *Maryland Register*. Since then stakeholders have been moving forward with the development of self-screening assessment tools and prescription algorithms, in preparation for pharmacists to be able to prescribe contraceptives as soon as January 1, 2019.

MPhA also participated in a stakeholder working group requested by Del. Terri Hill to provide pharmacist input on legislation to streamline the ***prior authorization*** process for medications and durable medical equipment.

Are You or a Colleague Struggling?

The Maryland Board of Pharmacy Rehabilitation Services is available to any pharmacist, pharmacy technician, or intern in need of treatment and/or rehabilitation for

- alcoholism
- drug abuse
- chemical dependency
- or other physical, emotional or mental conditions

Call or refer those in need to 1-833-329-2482. Services are available now.

MPhA's Call for Abstracts Being Accepted for Future CE Programs!

MPhA is currently seeking abstracts for future CE programs. You are encouraged to submit an abstract to share your knowledge and expertise with your peers. Innovative and engaging content will enhance the profession and the practice of pharmacy in Maryland. Please submit abstract and learning objectives at https://bit.ly/2xddS1l.

MPhA Foundation Elects New Board

Congratulations to the newly elected members of the MPhA Foundation Board. MPhA looks forward to working collaboratively with the Foundation and its leadership.

President
G. Lawrence Hogue

Vice President
Matthew Shimoda

Secretary
Aliyah N. Horton

Directors
Michelle Andoll
Christine Lee-Wilson
Hoai-An Truong
James L. Bressette

Thank you to past Foundation Board Members: Alfred Abramson, Douglas Campbell, Murhl Flowers, Arnold Honkofsky, Howard Schiff, Kristen Fink, and Mark Levi

Special thank you to Paul Holly, immediate past president and Cynthia Boyle for your assistance in the leadership transition.

A minimum contribution of $25 to the Foundation, entitles membership in the Foundation. Visit www.marylandpharmacist.org for more information and to make a tax-deductible contribution. Contributions may also be made during your membership dues renewal process.

MPhA
MARYLAND PHARMACISTS ASSOCIATION

Welcomes

OUR NEWEST MEMBERS

Roma Amin

Yadessa Chawaka

Patricia Kernick

SAVE THE DATES

October 18
Board of Trustees Meeting

October 25
Introduction to Drug Safety Surveillance and the FDA Adverse Event Reporting System

November 15
Board of Trustees Meeting

December 17
MPhA Holiday Party

January 17
Board of Trustees Meeting

February 7, 2019
Maryland Pharmacy Coalition Legislative Day, Annapolis

February 10, 2019
2019 Mid-Year Meeting, Hyattsville, MD

June 21 – June 24, 2019
137th Annual Convention, Ocean City, MD

For more information and additional activities visit www.marylandpharmacist.org.

Maryland's Pharmacists: Improving People's Health

By 2025, the U.S. could see a shortage of as many as 31,100 primary care physicians.
Even if nurse practitioners and physician assistants are fully utilized, patient needs will not fully be met.[1]

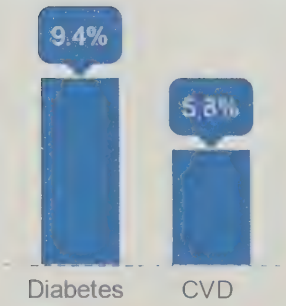
Maryland has 60 designated HPSAs and only 47% of the primary care needs in those areas are currently being met.[2] There are 6,290 highly trained pharmacists in MD who are ready to provide valuable healthcare services.[3]

Meeting Patients' Needs in Maryland

6 million people[4]

231 more primary care providers are needed[5]

6,290 Pharmacists ready to help[6]



Prevalence of chronic disease in Maryland [9]

Diabetes

Diabetes is a complex condition that is often managed by multiple medications. Pharmacists can optimize care and help patients understand their medications and their condition in order to improve outcomes and avoid complications.[7]

Cardiovascular Disease (CVD)

For patients with uncontrolled high blood pressure, waiting even two months to optimize medications increases the risk of complications, including hospitalizations. Pharmacists are highly accessible members of the care team who significantly improve blood pressure control and can provide timely follow-up and monitoring to improve outcomes.[8]

49% of Maryland residents were vaccinated for the flu[10]

Immunization rates across the U.S. have continued to increase since pharmacists began vaccinating.[11]

50% of people with chronic diseases do not take their medicines correctly.[14]

14% of people in Maryland smoke cigarettes[12]

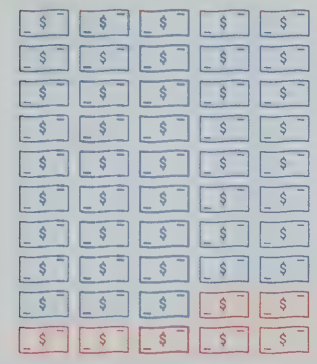
Smoking causes nearly 1 of every 5 deaths in the U.S. each year.[13] Pharmacists are qualified and capable of providing smoking cessation counseling.

Medications are critical for the treatment of chronic conditions. Pharmacists can help patients use them safely and effectively to avoid medication related problems.

Maryland spends $6,847,000,000 annually on prescription medications.[15]

Investing in pharmacists' services optimizes the use of those prescription medications. Decades of research have proven the value of including pharmacists on healthcare teams. Improved health outcomes, lower costs, and increased access to care could be a reality for Maryland residents if pharmacists were fully empowered to serve as patient care providers.

Healthcare $$ Spent on Chronic Conditions



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On average **$1,000** per patient per year is saved with pharmacist interventions for patients with chronic conditions.[17]

Pharmacists' counseling and adherence programs can save the healthcare system **$164** per patient in the 6 months following the start of a new prescription medication.[18]

16% of patients are readmitted after being discharged from a Maryland hospital.[19]

Patients are **2X** more likely to stay out of the hospital when pharmacists provide clinical services after discharge.[20]

Maryland spent $4.1 billion on Medicaid in 2016.[22]

Pharmacists in Ohio delivered a 4.4:1 ROI when providing medication therapy management services to Medicaid patients. Maryland pharmacists could do this too![21]

$4.40 saved per $1 spent on pharmacists' services

This information was developed through a collaboration between APhA and NASPA with generous support from the Community Pharmacy Foundation.

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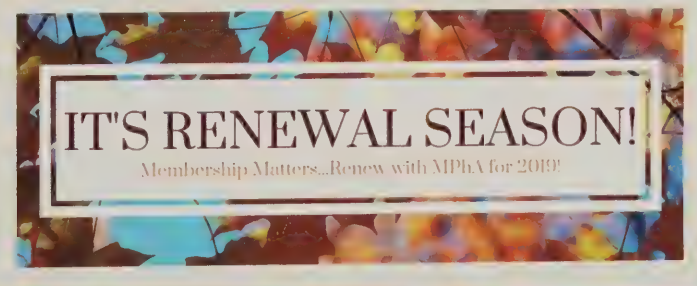
TOP 10 Reasons to Renew with MPhA

1. **Strengthen Your Career** — MPhA members enjoy educational opportunities designed to increase knowledge and keep up with the latest information.
2. **Advance Patient Care** — The more you learn about drug and treatment updates through our quarterly journal, the Maryland Pharmacist; biweekly e-newsletter; as well as through attending OUR MPhA meetings, the better equipped you are to help your patients.
3. **Network with Others in Your Field** — MPhA members are invited to join their colleagues, with discounted registration rates, at the 2019 Mid-Year Meeting and 137th Annual Meeting & Convention.
4. **Advocate for Your Profession** — By renewing with MPhA, you are supporting the only organization representing the voice of all pharmacists. During the past year, MPhA's work on health care legislation and regulations increased policy makers' awareness of the pharmacist's role in health care and the impact of pharmacy reimbursements on patient's access to care. MPhA continues to work on YOUR behalf.
5. **Proclaim Your Professionalism** — Keeping your name in the ranks of the colleagues who are members declares your pride in the profession. Support MPhA's advocacy efforts as we work with policy makers to implement legislation and impact regulations to positively support and protect the profession and practice settings.
6. **See It All** — MPhA is the only state-wide pharmacy organization that represents all pharmacists — you can learn about all the opportunities available within pharmacy and gain insight from pharmacists representing a variety of practice settings.
7. **Develop Your Leadership Skills** — Participate as an active leader in a variety of committees and volunteer leadership positions that will develop your skills as you give back to your profession.
8. **Make a Positive Impact** — By joining MPhA, you are taking a step to insure the future of the profession in Maryland. We can't do this important work without YOU.
9. **Make the Connection** — MPhA works with many industry partners that offer discounts or important expertise that can positively impact your pharmacy or practice setting.
10. **Gain the Competitive Edge** — MPhA gives you access to unique experiences, career information, and resources designed to meet your needs and provide support as you advance in your career.



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Continuing Ed

Mothers To Be: Are They Getting Enough Vitamin D?

Brittany Speed, PharmD Candidate; Lauren G. Pamulapati, PharmD, BCACP; Nicole E. Omecene, PharmD, BCPPS

All authors are from the Virginia Commonwealth University School of Pharmacy

After completing this activity, the pharmacist will be able to:

1. Describe the guidelines regarding vitamin D supplementation during pregnancy.
2. Recognize the prenatal and postnatal effects of vitamin D deficiency during pregnancy.
3. Identify clinical controversies regarding vitamin D use during pregnancy.
4. Given a patient case, determine recommendations for vitamin D intake and supplementation during pregnancy.

After completing this activity, the technician will be able to:

1. Identify the role of vitamin D supplementation during pregnancy.
2. Recognize the prenatal and postnatal effects of vitamin D deficiency during pregnancy.
3. Identify controversies regarding vitamin D use during pregnancy.

Keywords:
vitamin D deficiency
pregnancy
maternal outcomes
fetal outcomes

Introduction

Many pregnant women are deficient in vitamin D despite its presence in prenatal vitamins.[1-3] There is a strong correlation between vitamin D levels in pregnant women and the vitamin D levels seen in their newborns.[4-7] Consequently, infants born to mothers at high risk for vitamin D deficiency are also at risk of deficiency and postnatal complications including hypocalcemic seizures, asthma, and obesity.[7-17] Vitamin D deficiency in pregnancy may also increase the risk of preeclampsia, gestational diabetes, and low birthweight, which may lead to negative effects for both the mother and child.[18-24] While deficiency is preventable with supplementation, clinical controversy exists regarding the optimal vitamin D supplementation needed during pregnancy to optimize outcomes for mothers and their infants.

Vitamin D is a fat-soluble secosteroid that plays a major role in physiologic functions such as bone mineralization, calcium homeostasis, and immune function. Vitamin D is an inactive pro-hormone that is synthesized in the skin upon exposure from sunlight and can also be obtained through diet.[25] It is found in two major forms, D_2 (ergocalciferol) and D_3 (cholecalciferol), both of which are manufactured as dietary supplements. While Vitamin D_3 can be obtained from diet and from the conversion of 7-dehydrocholesterol in the skin via ultraviolet B (UV-B) radiation, vitamin D_2 cannot be obtained via UV-B radiation. Both forms require activation by two enzymatic hydroxylation reactions: first to 25-hydroxyvitamin D (25(OH)D) via the liver, then to 1,25-dihydroxyvitamin D (1,25(OH)2D) via the kidney.[26] While 1,25(OH)2D is the active, hormonal form, the half-life is very short (15 hours) and the serum concentration is regulated by the parathyroid hormone, calcium, and phosphate. Therefore, 25(OH)D, with a half-life of approximately 15 days, is used as a surrogate marker of vitamin D level.[27,28]

A normal vitamin D concentration is considered to be between 20 ng/mL – 50 ng/mL.[27] The Food and Nutrition Board at the Institute of Medicine (IOM) of the National Academies states that the recommended dietary allowance (RDA) of vitamin D during pregnancy and lactation should be about 600 international units (IU) per day.[27] Aside from dietary supplements, sources of vitamin D include fortified foods such as milk, natural foods such as egg yolks and fatty fishes, and exposure to sunlight. However, the RDA assumes minimal sun exposure as several factors can limit the production of vitamin D via UV-B penetration of the skin, including season, use of sunscreen, skin pigmentation, clothing, and other barriers such as windows.[27] Pregnant women often receive some of their RDA from prenatal supplements, which are discussed below.

The American College of Obstetricians and Gynecologists (ACOG), which provides the standard of prenatal care in the United States, also recommends 600 IU of vitamin D daily.[29] To meet the RDA, ACOG recommends supplementation with a daily prenatal vitamin; however, many

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prenatal vitamins only contain 400 IU of vitamin D per dose, thus the remaining 200 IU must come from other sources. For women who are pregnant, screening for vitamin D is not recommended outside of patients deemed high risk per ACOG.[29] High-risk groups include, but are not limited to, vegetarians, women with limited sun exposure, individuals with darker skin, and women delivering during the winter months.[1,7,19] However, ACOG does not provide guidance on screening these high-risk individuals nor do they provide recommendations on when and how to treat vitamin D deficiency in pregnancy. It has also been shown that women who gain more weight during pregnancy are at higher risk for lower vitamin D levels during pregnancy compared to other women who gain less weight during pregnancy, despite both receiving the same amount of supplementation.[30]

Conversely, the World Health Organization (WHO) stated that supplementation of vitamin D is not required to improve maternal and fetal outcomes and only recommends 200 IU per day in patients with documented deficiency.[31] While ACOG and WHO recognize that vitamin D deficiency in pregnancy is an increasing problem, neither believes there is sufficient evidence to change current recommendations. On the other hand, there is mounting evidence to suggest that vitamin D deficiency may increase adverse outcomes for the mother and fetus into infancy and childhood. Some of the evidence will be reviewed regarding these outcomes due to vitamin D deficiency during pregnancy and to provide recommendations for clinical practice of vitamin D supplementation during pregnancy.

Maternal and Fetal Outcomes Due to Vitamin D Deficiency

One of the rationales regarding the need for vitamin D supplementation is prevention of maternal and fetal adverse outcomes. Much like with the controversy over the amount of vitamin D supplementation that is sufficient, there is debate over the effect of vitamin D deficiency on maternal outcomes, such as pre-eclampsia and gestational diabetes, and fetal outcomes, such as fetal growth.[5,18,20,22-24] As preeclampsia is the most commonly discussed maternal outcome related to vitamin D deficiency, the focus of this section will be on preeclampsia.

Gestational hypertension is a dangerous condition in pregnancy, characterized by high blood pressure after 20 weeks gestation. Once proteinuria becomes present, the woman is defined as having preeclampsia. Vitamin D is thought to modulate inflammation and immune function, which are involved in maternal tolerance to the foreign fetus and impacts optimal implantation.[18,25,32] Increased inflammation caused by disruption of endothelial stability, theoretically leads to placental damage, thus increasing the risk of preeclampsia.[18] It is proposed that vitamin D_3 given at physiological doses would stabilize the endothelium, thus reducing the risk of preeclampsia.[18]

In a study published in the *Journal of Nutrition* by Bodnar and colleagues examining nulliparous pregnant singleton women (n=274), maternal vitamin D deficiency at less than 22 weeks was determined to be an independent risk factor for preeclampsia (p=0.02), and 25(OH)D concentrations <15.2 ng/mL during early-pregnancy were associated with a 5-fold increase in the odds of preeclampsia (adjusted OR, 5.0; 95% CI, 1.7-14.1). These findings were independent of proposed risk factors for preeclampsia, including: race/ethnicity, season, gestational age, pre-pregnancy BMI, and education.[5] After adjustment for these factors, a 20 ng/mL decline in 25(OH)D concentration doubled the risk of preeclampsia (adjusted OR, 2.4; 95% CI 1.1-5.4).[5] These findings are supported by a systematic review and meta-analysis that found women with a 25(OH)D level <20 ng/mL are at an increased risk for preeclampsia.[22]

Recognizing that vitamin D deficiency is related to preeclampsia, Roth and colleagues sought to determine if vitamin D supplementation during pregnancy could prevent maternal, neonatal, and infant adverse outcomes. This systematic review and meta-analysis found insufficient evidence to prove supplementation with vitamin D prevented preeclampsia (risk ratio, 0.82; CI, 0.63 to 1.07; 16 comparisons; 3398 participants) or gestational hypertension (risk ratio, 0.82; CI, 0.53 to 1.30; 8 comparisons; 2430 participants).[20]

The Vitamin D Antenatal Asthma Reduction Trial (VDAART) study by Mirzakhani and colleagues was one of the studies included in this meta-analysis. The primary aim of this study was to characterize the effect of vitamin D supplementation during pregnancy on a child's risk of developing asthma, which will be discussed in more detail in a later section. The trial also included secondary outcomes, including the effect of early pregnancy vitamin D supplementation at 10 to 18 weeks and both early and late pregnancy 25(OH)D levels on the risk of preeclampsia.[21] Low 25(OH)D levels in early pregnancy, as well as throughout pregnancy, were associated with a higher incidence of preeclampsia. Women who were supplemented with 4,400 IU of vitamin D showed an increase in 25(OH)D levels during the third trimester; however, there

was no reduction in the rates of preeclampsia compared to the placebo group receiving 400 IU of vitamin D. Reduced rates of preeclampsia were found in women who had vitamin D levels > 30 ng/mL maintained through both early (10 to 18 weeks of gestation) and late (32 to 38 weeks of gestation) pregnancy, regardless of the treatment group the patient was assigned (adjusted OR, 0.96; CI, 0.08-0.96; P=0.04). Early pregnancy 25(OH)D levels were a strong predictor of preeclampsia (adjusted OR, 0.96; CI, 0.93-0.99, P=0.025), with incremental increases in 25(OH)D levels associated with reduced preeclampsia risk. The lowest risk was found among women with vitamin D levels of 40 ng/mL during early pregnancy. Based on these findings, the authors postulated that supplementation with vitamin D prior to implantation of the embryo is necessary to reduce the risk of preeclampsia. They recommended screening for vitamin D deficiency in all pregnant women considered at high risk for vitamin D deficiency or at risk for vitamin D supplementation non-adherence and pre-pregnancy supplementation should be provided to support adequate vitamin D levels prior to implantation, with continued individualized doses provided throughout pregnancy to maintain adequate vitamin D serum concentrations.[21]

Preeclampsia can cause preterm birth (PTB), birth before the 37th week of gestation. However, regardless of preeclampsia, PTB has also been linked to women with low vitamin D levels. PTB is commonly caused by infections or inflammation, which as discussed previously, can be attenuated by adequate vitamin D serum concentrations.[33] A meta-analysis of observational studies found that pregnant women with 25(OH)D levels <20 ng/mL had an increased risk of PTB (OR, 1.29; 95% CI, 1.16-1.45). These observational findings were confirmed in a *post hoc* analysis by Wagner and colleagues of two combined vitamin D cohorts (N=509), in which vitamin D supplementation was provided at doses of 2,000 IU and 4,000 IU.[4,34] In this analysis, achieving a 25(OH) D serum concentration >40 ng/mL (n=233) significantly reduced PTB rates compared to serum concentrations <20 ng/mL (n=82; RR=0.4; 95% CI, 0.22-0.83).[35] The largest impact on reduction of risk was among Hispanic women and individuals with baseline 25(OH) D <20 ng/mL. When this data was compared to the Charleston County, South Carolina March of Dimes rates of PTB, Hispanic and Black women with 25(OH)D levels >40 ng/mL within six weeks of delivery had a statistically significant decrease in preterm birth rates of 66% (p=0.01) and 58% (p=0.04), respectively. The authors concluded that to reduce risk of PTB, women should, at a minimum, maintain 25(OH)D levels above 20 ng/mL; however, targeting levels greater than 40 ng/mL was preferred. To achieve this concentration, many women would require supplementation above the IOM's RDA for vitamin D of 600 IU/day.[35]

Small for gestational age (SGA) is a term used to describe infants with weights below the 10th percentile for gestational age and has also been linked to low 25(OH)D levels. A meta-analysis in *JAMA Pediatrics* found that in six randomized controlled trials (898 participants) vitamin D supplementation resulted in a significantly lower risk of SGA births (RR, 0.72; 95% CI, 0.52-0.99, I2=0%).[24] A subgroup analysis found that supplementation doses of <2,000 IU/day was associated with a reduced risk of SGA (RR, 0.45; 95% CI, 0.23-0.90), whereas, there was no associated risk reduction with supplementation doses >2,000 IU/day (RR, 0.83; 95% CI, 0.57-1.19).[24] Intake of milk, which is fortified with vitamin D in the United States, during pregnancy has been associated with higher birth weight for gestational age and lower risk of SGA.[36] Conversely, placental abruption, preeclampsia, and gestational diabetes are risk factors for SGA, all of which have also been linked to vitamin D deficiency.[37] These findings further reinforce that adequate vitamin D serum concentrations during pregnancy play an important role for both mother and baby.

Gestational diabetes mellitus (GDM), glucose intolerance that develops or is first recognized during pregnancy, has also been considered a potential adverse outcome of vitamin D deficiency during pregnancy. A recent meta-analysis found that vitamin D deficiency is related to an increased risk of GDM (OR, 1.18; 95% CI, 1.01-1.35; p<0.001); however, due to the limited increased risk (18%) compared to previous meta-analyses, the authors could not conclude definitively that vitamin D deficiency increased the risk of GDM. Therefore, they suggested that that vitamin D deficiency *may* increase the risk of GDM.[23] The authors also note that vitamin D deficiency is affected by many other factors that independently contribute to GDM, thus it is difficult to characterize the true effect of vitamin D deficiency in relation to GDM risk.

Vitamin D Deficiency and Postnatal Outcomes

It has been established that maternal vitamin D deficiency can lead to problematic outcomes relating to bone development, including an increased risk of congenital rickets.[5,9,10] Recent interest lies in the non-classical functions of

vitamin D including immunological, respiratory, metabolic, and neurological outcomes. For example, animal studies have suggested increased risk of obesity in mice born to vitamin D deficient mothers.[38,39] Human studies assessing maternal vitamin D deficiency and offspring obesity are observational in nature and examine a variety of different obesity-related outcomes, but suggest there is a modest association and increased risk of obesity.[11-13] These studies highlight the important potential roles that vitamin D screening and supplementation during pregnancy can play in mitigating the growing public health concern of obesity. Further research is required to gain more insight, especially because changes in vitamin D levels over time during childhood is a major possible confounding variable.

Another potential postnatal complication of vitamin D deficiency in pregnancy is neonatal hypocalcemic seizures. As stated previously, maternal vitamin D levels are highly predictive of neonatal levels. Infants born to vitamin D deficient mothers may become deficient faster than an infant born to a mother with sufficient vitamin D levels.[1] Calcium and vitamin D have a complex relationship in bone homeostasis, but a major function of vitamin D is to increase the intestinal absorption of calcium.[40] Neonates exhibit rapid growth early in life, including a high rate of skeletal growth, which makes them vulnerable to hypocalcemia. If the neonate is also deficient or develops a deficiency of vitamin D due to inadequate supplementation, this could potentially reduce the absorption of calcium and cause hypocalcemia increasing their risk of experiencing hypocalcemic seizures. Three studies have demonstrated an association between maternal vitamin D deficiency and development of neonatal hypocalcemic seizures, introducing another area for research where maternal supplementation of vitamin D may be beneficial.[41-43]

Lung and immune system development occur both in utero and throughout early childhood. It has been postulated that vitamin D plays a role in the development of the pulmonary and immune systems during the fetal and early postnatal periods. Therefore, vitamin D status has been an area of interest as a modifiable risk factor for the development of asthma and allergies in early childhood.

Four major studies evaluated childhood respiratory and allergic outcomes with maternal vitamin D supplementation. The VDAART was a randomized, double-blind, placebo-controlled trial aimed at determining if vitamin D supplementation in pregnancy could prevent the development of asthma or recurrent wheezing in early childhood.[14] Eligible participants (n=876) were between 10 and 18-weeks gestation with a history of asthma, eczema, or allergic rhinitis or whose partner had one of these characteristics. The intervention group received 4,000 IU, in addition to the 400 IU found in the prenatal vitamin (n=440), while the control group received only the 400 IU from the prenatal vitamin (n=436).[14] The first primary outcome assessed parental report or physician diagnosis of asthma or recurrent wheezing in the first three years of life. Ninety-eight children (24.3%; 95% CI, 18.7-28.5) developed asthma or recurrent wheezing in the intervention group compared to 120 children (30.4%; 95% CI, 25.7-73.1) in the control group (HR, 0.8; 95% CI, 0.6-1.0; non-parametric P=0.051).[14] This resulted in a non-statistically significant 6% absolute reduction in the development of asthma or recurrent wheeze. For the other primary outcome, 74.9% compared to 34% achieved the endpoint of maternal 25(OH)D levels >30 ng/mL, in the intervention group and control group, respectively (difference, 40.9%; 95% CI, 34.2-47.5%, P<0.001).[14] Despite finding a significant increase in the maternal third trimester 25(OH)D levels, the study may have been underpowered to identify a benefit of maternal vitamin D supplementation with regard to respiratory and allergic outcomes in early childhood.

Similar findings were reported in another double-blind, single center study and a meta-analysis.[15,16] The Copenhagen Prospective Studies on Asthma in Childhood 2010 (COPSAC 2010) trial supplemented 2,800 IU of vitamin D in the intervention group compared to 400 IU in the control group, which failed to show a significant reduction in the risk of persistent wheeze in the first three years of life.[16] However, the authors believed the protective effect should not be ruled out definitively based on a large confidence interval, post-hoc analyses, and significant findings of the secondary outcomes, including a reduction in "troublesome lung symptoms" and significantly increased up-regulation of immune mediators, which are thought to be protective against occurrence of wheeze. COPSAC 2010, like VDAART, may also have been underpowered to detect a difference in the primary outcome. Unlike VDAART, they chose a lower vitamin D dose for supplementation and enrolled patients after 22 weeks gestation. Conversely, the VDAART trial examined earlier intervention with higher maternal vitamin D doses and still did not show a benefit on asthma-like outcomes in children. The meta-analysis by Pacheco-Gonzalez included 16 studies (including VDAART and COPSAC 2010) examining the relationship between asthma risk in offspring from three to 14 years of age and prenatal vitamin D levels.[15] An inverse association was found between vitamin D and risk of asthma, but it did not reach statistical significance (95% CI, 0.78-1.06; P=0.217).[15] The authors noted that there was a moderate-high degree of heterogeneity across the trials included in the analysis for wheeze.

On the other hand, more recently, Wolsk and colleagues performed a meta-analysis including only the VDAART and COPSAC 2010,

which are the two largest trials to date assessing vitamin D supplementation in pregnancy, to assess the impact of vitamin D supplementation on wheeze.[17] They did not find significant heterogeneity between the trials (I^2=0%, p=0.89). Combined, there was a statistically significant 26% reduction in asthma/recurrent wheeze in the intervention group versus the control group (OR = 0.74; 95% CI, 0.57-0.96). After stratifying women with levels greater than or less than 30 ng/mL at baseline, there was a protective effect against asthma when the women had a 25(OH)D level >30 ng/mL earlier in pregnancy. Combining these two trials provided adequate power to detect a benefit of vitamin D supplementation in pregnancy for the prevention of childhood asthma and provides important evidence for the ongoing debate regarding additional vitamin D supplementation in pregnancy.

Clinical Controversy Regarding Vitamin D Supplementation in Pregnancy

Currently, there is a lack of consensus in the medical community on whether vitamin D screening and additional supplementation in pregnancy is necessary to reduce negative outcomes in both pregnant women and their offspring. As stated previously, neither ACOG nor the WHO recommends screening or additional supplementation beyond what has been discussed above, at this time; however, they allude to the idea that supplementation beyond the RDA is relatively safe in pregnancy. In their review of vitamin D supplementation in pregnancy, Hollis and Wagner argue that there is not only sufficient evidence to support supplementation, but also that vitamin D status during pregnancy is a very important factor that contributes to maternal, fetal, and infant outcomes.[18] Currently, ACOG recommendations are based on the IOM RDA; however, there is evidence to suggest that the IOM RDA of 600 IU/day of vitamin

Active Learning/Patient Case

L.S., a 36 YO AAF, with PMH of asthma and preeclampsia with a previous pregnancy, presents to your clinic. She is 10 weeks pregnant and interested in ensuring she has a healthy pregnancy. She seeks advice on vitamin D supplementation because after her last pregnancy, she heard she may have been at higher risk for preeclampsia due to potential vitamin D deficiency. L.S. lives in an urban area, her diet consists of mostly processed foods with little dairy or fresh fruits and vegetables. Her current medications include: prenatal vitamins, albuterol inhaler 90mcg/inh 2 puffs q4-6 hr PRN. She denies OTC medications.

1. What is the target 25(OH) D level per the Institute of Medicine (IOM)?

a. >10 ng/mL
b. >20 ng/mL
c. >30 ng/mL
d. >40 ng/mL

2. The patient is currently on a prenatal vitamin, assuming the patient is not receiving vitamin D from other sources, what is the vitamin D deficit according to ACOG?

a. 200 IU
b. 400 IU
c. 600 IU
d. No deficit

3. You have identified the patient has a diet low in vitamin D. What would be the best recommendation for the patient to incorporate into their diet to ensure optimal vitamin D supplementation from food sources?

a. Fortified Milk
b. Seafood
c. Fresh fruits and vegetables
d. Whole grains

4. As a clinician, would you consider additional supplementation (beyond the prenatal vitamin) in this patient?

a. No, the patient is not considered high risk for vitamin D deficiency
b. No, the risks of vitamin D supplementation outweigh the benefits
c. Yes, depending on the patient's current vitamin D serum concentration
d. Yes, new evidence suggests all patients should receive additional supplementation

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D may not be enough to achieve sufficient vitamin D levels in women with insufficient or deficient serum concentrations at baseline.[4] Nutrient trials are more cumbersome compared to drug trials, as patients have varying levels of vitamin D at baseline and can vary greatly on intake of and exposure to vitamin D, which is difficult to control for in a trial. The WHO agrees that vitamin D deficiency is a common problem among pregnant women in certain populations and states that supplementation during pregnancy can improve maternal vitamin D status and may reduce the risk of preeclampsia, low birthweight, and preterm birth.[31] Despite these agreements, the WHO currently does not support vitamin D supplementation in pregnant women. Instead, they encourage pregnant women to receive adequate nutrition through consumption of a healthy balanced diet while waiting on ongoing trials examining vitamin D in pregnancy. Even so, it remains unclear what dose of vitamin D in pregnancy or what 25(OH)D serum concentration is needed to reduce negative outcomes. Previous recommendations from the Food and Nutrition Board state that the upper limit for vitamin D supplementation in pregnancy is 2000 IU daily; however, others have opposing views.

Hollis and colleagues examined the effects of vitamin D doses of 400, 2,000, or 4,000 IU given to pregnant women (N=350) at 12 to 16 weeks gestation until delivery. The primary outcome was maternal and neonatal serum 25(OH)D concentrations at delivery, and a secondary outcome of achieving 25(OH)D concentration >32 ng/mL. There was a statistically significant difference in the 25(OH) D concentration between the treatment groups at one month prior to delivery and at delivery ($p<0.0001$).[4] The highest mean maternal and neonatal 25(OH) D concentration was achieved in the 4,000 IU group at each time point.4 The relative risk for achieving 25(OH)D serum concentrations greater than 32 ng/mL within one month of delivery was significantly different between 2,000 IU and 400 IU groups (RR,1.52; 95% CI, 1.24-1.86) and 4,000 IU vs 400 IU groups (RR, 1.60; 95% CI, 1.32-1.95) but not between 4,000 IU and 2,000 IU groups (RR, 1.06; 95% CI, 0.93-1.19).[4] The authors found no difference in safety measures between groups, and no adverse events were attributed to vitamin D supplementation.[4] This study suggests that vitamin D supplementation with 4,000 IU is the most effective to achieve sufficient 25(OH)D concentrations without an increased risk of vitamin D toxicity.

Data on higher doses are lacking, but experts agree that supplemental vitamin D is safe up to 4,000 IU per day during pregnancy.[4,14] The optimal target for 25(OH) D concentrations in pregnancy and what constitutes sufficiency is unknown, but it is generally accepted that >20 ng/mL is sufficient for bone health and even >40 ng/mL to avoid maternal comorbidities.[4,27]

The controversy on vitamin D supplementation also extends to breastfeeding and vitamin D supplementation of the infant, which is beyond the scope of this article but is an important consideration. Briefly, exclusively breastfed infants are especially at risk for vitamin D deficiency because breast milk is not an adequate source of vitamin D.[44] Moreover, lactating women who are deficient in vitamin D transfer less vitamin D into their milk, further increasing the need to supplement exclusively breastfed infants.[45] The Academy of Breastfeeding Medicine recommends supplementing either the infant or the mother with vitamin D to prevent deficiency and vitamin D deficiency-related complications, but there is not a definitive method that is preferred over the other.[46] The current recommendation is to supplement at least 400 IU/day to the infant or 6,400 IU/day to the mother to achieve normal vitamin D status in both the mother and infant.[46]

Conclusion

After review of the available evidence of vitamin D in pregnancy, it appears that the benefit of additional supplementation outweighs the risk of toxicity. In the pregnant woman, sufficient levels of vitamin D suggest a reduction in maternal and fetal outcomes including preeclampsia, low birth weight, and gestational diabetes, and a reduction in infant outcomes including asthma, obesity, and neonatal seizures. No adverse effects were reported in any of the trials when supplementation up to 4,000 IU was used as an intervention. Current evidence examined vitamin D supplementation after at least 10 weeks of gestation so the effects of supplementation on organogenesis (i.e. eight weeks after fertilization) still remain unknown. This strongly supports the idea that there is potential to improve outcomes in pregnancy with vitamin D supplementation during the second and third trimesters without a coinciding risk of toxicity or harm to the fetus or infant. It is true that the available evidence is not as robust as practitioners would prefer, which is likely why the recommendations from ACOG and WHO remain as described above; however, there are several potential benefits to supplementation in deficiency. Moreover, toxicity with supplementation in pregnancy has yet to be reported. A search of clinicaltrials.gov reveals 30+ trials examining vitamin D in pregnancy with hopes to provide more sound evidence to support this practice of vitamin D supplementation in pregnancy. As such, all pregnant women, especially those at high risk for deficiency, could be considered for screening and subsequently supplemented with additional vitamin D beyond what is included in their daily prenatal vitamin.

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ANSWERS: Active Learning/Patient Case

1. Answer: B
Rationale: According to the IOM, greater than or equal to 20 ng/mL is generally considered necessary for optimal bone and overall health (answer B). However, the IOM does not differentiate between non-pregnant and pregnant adults for target values. Some believe that a minimum of 30 ng/mL is necessary to prevent maternal and fetal negative outcomes with the optimal target being >40 ng/mL.

2. Answer: A
Rationale: A prenatal vitamin contains 400 IU of vitamin D. ACOG recommends patients receive 600 IU of vitamin D per day. This is the same recommendation as the recommendation from the Food and Nutrition Board at IOM of the National Academies. Thus, a remaining 200 IU must come from food sources or sunlight.

3. Answer: A
Rationale: In the United States, milk products are fortified with approximately 100 IU of vitamin D per cup (answer A), thus if the patient were to consume at least one cup per day, she would be up to 500 IU of vitamin D per day, not accounting for other sources. As an added bonus, if the patient had the milk with cereal, she would be getting additional vitamin D, as many cereals are also fortified with vitamin D. Seafood could be a possible option, depending on what type of seafood; however, a blanket recommendation of seafood would not suffice. Seafood high in vitamin D content are cod liver oil, swordfish, salmon, and tuna fish. Pregnant women should not consume swordfish due to high mercury content. Much like with seafood, fresh fruits and vegetables are not all created equal in regards to vitamin D content. Some vegetables, such as Portobello mushrooms have high vitamin D content, depending on how much light the mushrooms were exposed to. Lastly, grain products provide very little vitamin D.

4. Answer: C
Rationale: This patient having a poor diet and with dark complexion puts the patient at risk for vitamin D deficiency. The current evidence suggests that additional supplementation beyond the 400 IU found in the prenatal vitamin will not only not cause harm but may have additional benefits, such as preventing preeclampsia in women with low vitamin D levels or reducing risk of asthma/wheeze in offspring, especially among parents with history of asthma. However, for this benefit to be seen, women must be vitamin D deficient; thus, the decision to supplement would depend on the patient's current vitamin D serum concentration (answer C). There is still controversy regarding what concentration to target with supplementation.

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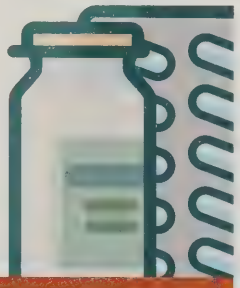

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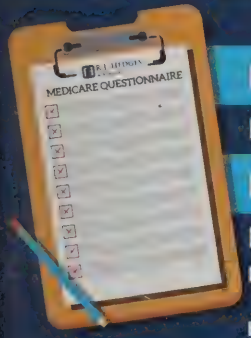

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Editorial

Third Quarter 2018: Pharmacy Time Capsule

By: Dennis B. Worthen, PhD, Cincinnati, OH

1993

- ACPE released proposed standards and guidelines for the PharmD as the professional entry-level degree.
- New Mexico passed legislation to address a shortage of primary care providers making it the first state to let specially trained pharmacists provide primary patient care.

1968

- Fentanyl, developed by Janssen and marketed by McNeil, was approved as an IV analgesic.

1943

- *Bulletin of the American Society of Hospital Pharmacists* first published. Later renamed *American Journal of Health-System Pharmacy*.

1918

- Beginning of the Spanish flu pandemic.

1893

- New Mexico formed state pharmacy association.

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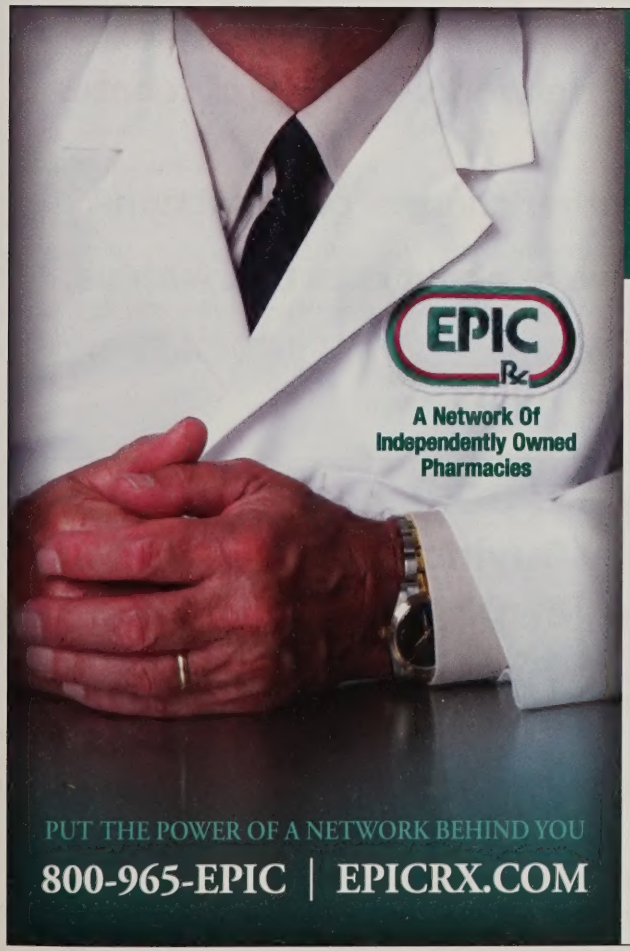

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Executive Director's Message

Happy Pharmacists Month and Pharmacy Technician Day!

Thank you for your service to your patients and contributions to public health in Maryland! Thank you to the MPhA leaders and volunteers who step forward to represent Maryland pharmacy.

With your input we continue to put the MPhA "stamp" on state and federal policy that specifically impacts how you practice. This year topics have covered the gamut: contraceptive prescriptive authority, PBM transparency and enforcement, drug disposal, pharmacy gag-rules, anti-drug importation, opioids, prior authorization, immunizations, drug supply chain, pharmacy reimbursements and so much more! Thank you for taking our calls to action and helping us make a difference.

Because of the depth and breadth of your access and influence, I encourage you to talk about what you do with your family and friends. It is a great time to show your community how important pharmacy is. Links to Pharmacists Month resources are available under the Hot Topics tab on the MPhA website. And stay tuned for new information we will be sharing about a national campaign to raise awareness about pharmacists roles in the community.

As this is "renewal season," know that I practice what I preach. I belong to my own professional associations. I am an active member of the American Society of Association Executives (ASAE). I have served on numerous taskforces and committees related to meeting content, public policy, and association certification. This engagement facilitates my learning of best practices and garners access to resources to better serve you. Over the years, I've presented at ASAE's Government Relations Symposium, Annual Convention and Online Conference for Small Associations. I am also a member of the National Alliance of State Pharmacy Associations (NASPA) and serve on the NASPA Pharmacy Services, LLC Board. NASPA is primarily comprised of state pharmacy association executives. We use our meetings to share best practices, stay up-to-date on pharmacy policy and repurpose advocacy and leadership lessons that are unique to the state pharmacy world. I find value in my interactions with my professional associations and the opportunity to give back. **I hope that you continue to find value in MPhA, will renew your membership, and will get engaged however best suits your needs and interests.**

As always, I look forward to seeing you at future MPhA activities and events. ●

Aliyah N. Horton, CAE
Executive Director

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